



US006911025B2

(12) **United States Patent**
Miyahara

(10) **Patent No.:** **US 6,911,025 B2**
(45) **Date of Patent:** **Jun. 28, 2005**

(54) **CONNECTOR SYSTEM FOR STERILE CONNECTION**

5,195,957 A 3/1993 Tollini
5,334,188 A * 8/1994 Inoue et al. 604/539
5,423,775 A * 6/1995 Cannon 604/533
5,792,120 A 8/1998 Menyhay

(75) Inventor: **Hideyasu Miyahara, Hiroshima (JP)**

(73) Assignee: **JMS Co., Ltd., Hiroshima (JP)**

(*) Notice: Subject to any disclaimer, the term of this patent is extended or adjusted under 35 U.S.C. 154(b) by 119 days.

FOREIGN PATENT DOCUMENTS

JP 6-312014 11/1994
JP 8-150216 6/1996
WO 94/08173 4/1994
WO 96/05882 2/1996
WO 97/35634 10/1997

(21) Appl. No.: **10/628,850**

* cited by examiner

(22) Filed: **Jul. 28, 2003**

Primary Examiner—Manuel Mendez

(65) **Prior Publication Data**

(74) *Attorney, Agent, or Firm*—Merchant & Gould P.C.

US 2004/0111078 A1 Jun. 10, 2004

(57) **ABSTRACT**

Related U.S. Application Data

A connector system for sterile connection includes a male type connector having a tube connecting portion at a rear end portion thereof, a protective cap for the patient side connector, an inner cap held in the protective cap and including a ring-shaped portion that supports a disinfectant-impregnated member therein, and a female type connector including an outer cylinder and an inner cylinder fixed at one end of the outer cylinder, where the inner cylinder includes an internal end portion located inside the outer cylinder and an external end portion exposed outside the outer cylinder. When the protective cap is fitted with the male type connector, the disinfectant-impregnated member contacts with the male type connector. When the protective cap is removed therefrom, the inner cap becomes retained in the male type connector. When such a male type connector is connected with the female type connector, the internal end portion of the inner cylinder penetrates through the disinfectant-impregnated member and a septum. When the connection is released, the inner cap is detached from the male type connector.

(63) Continuation-in-part of application No. 10/353,112, filed on Jan. 27, 2003.

(30) **Foreign Application Priority Data**

Jan. 25, 2002 (JP) 2002-017075

(51) **Int. Cl.**⁷ **A61M 5/32**

(52) **U.S. Cl.** **604/415; 604/905**

(58) **Field of Search** 604/905, 415, 604/284, 256, 244, 206, 167.01–167.06, 165.01–165.04, 91, 88, 86, 83; 285/331, 386

(56) **References Cited**

U.S. PATENT DOCUMENTS

3,986,508 A * 10/1976 Barrington 604/411
4,511,359 A * 4/1985 Vaillancourt 604/411
4,610,469 A 9/1986 Wolff-Mooij
4,878,516 A 11/1989 Mathieu
5,190,534 A 3/1993 Kendell

12 Claims, 9 Drawing Sheets

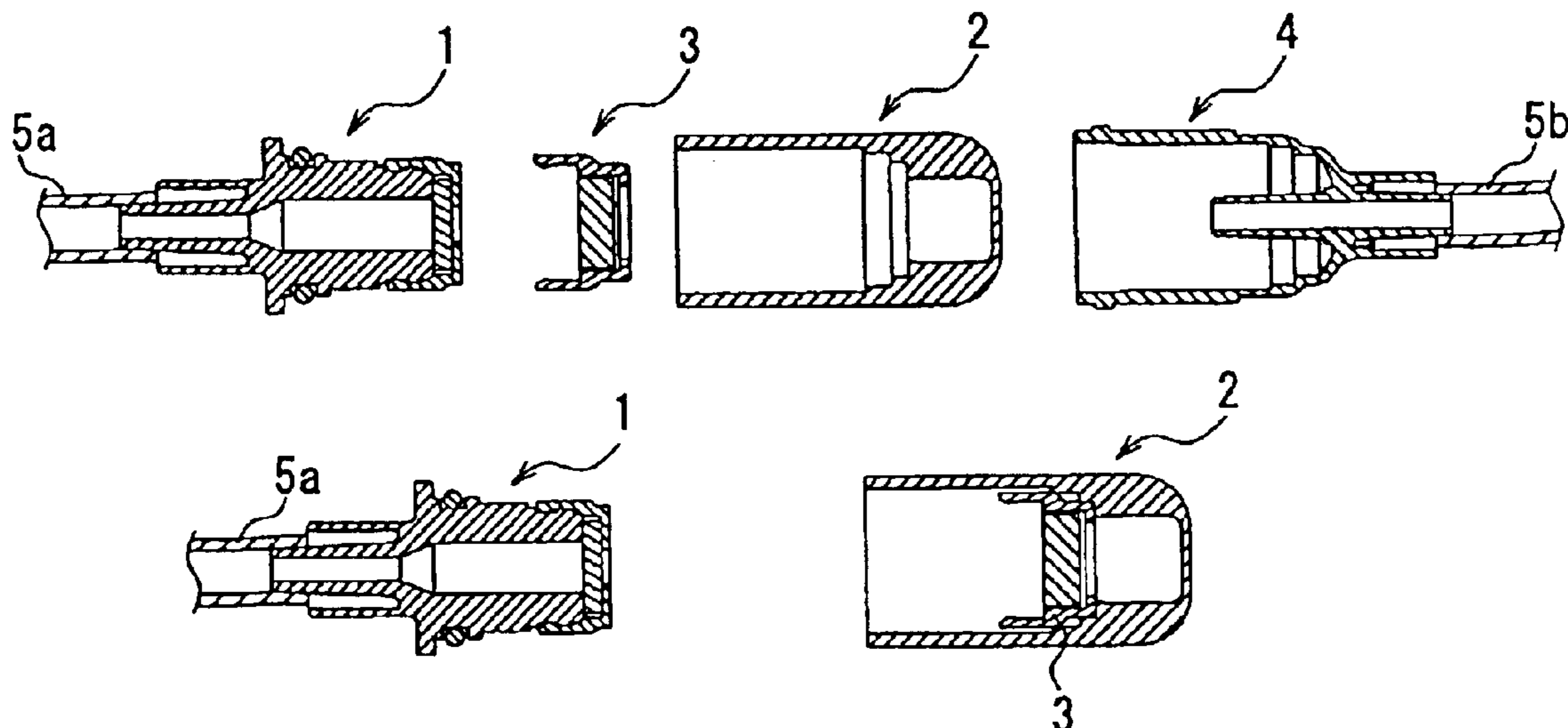


FIG. 1A

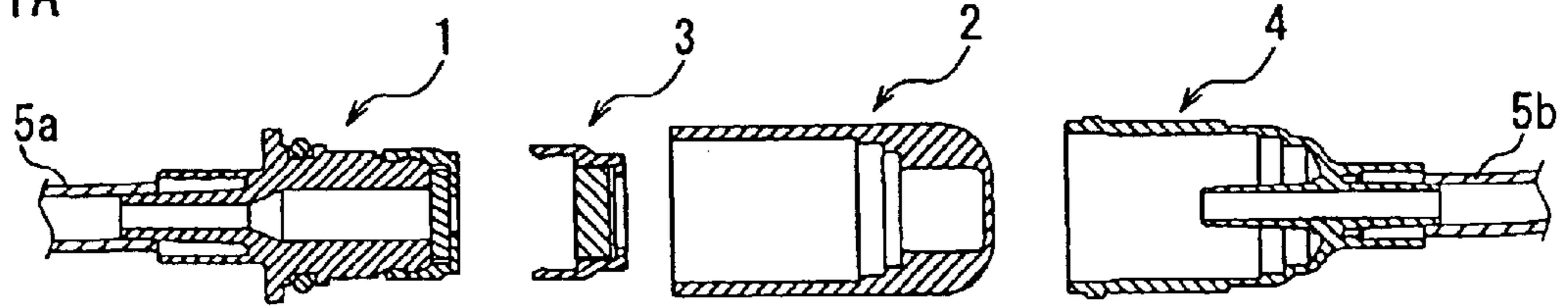


FIG. 1B

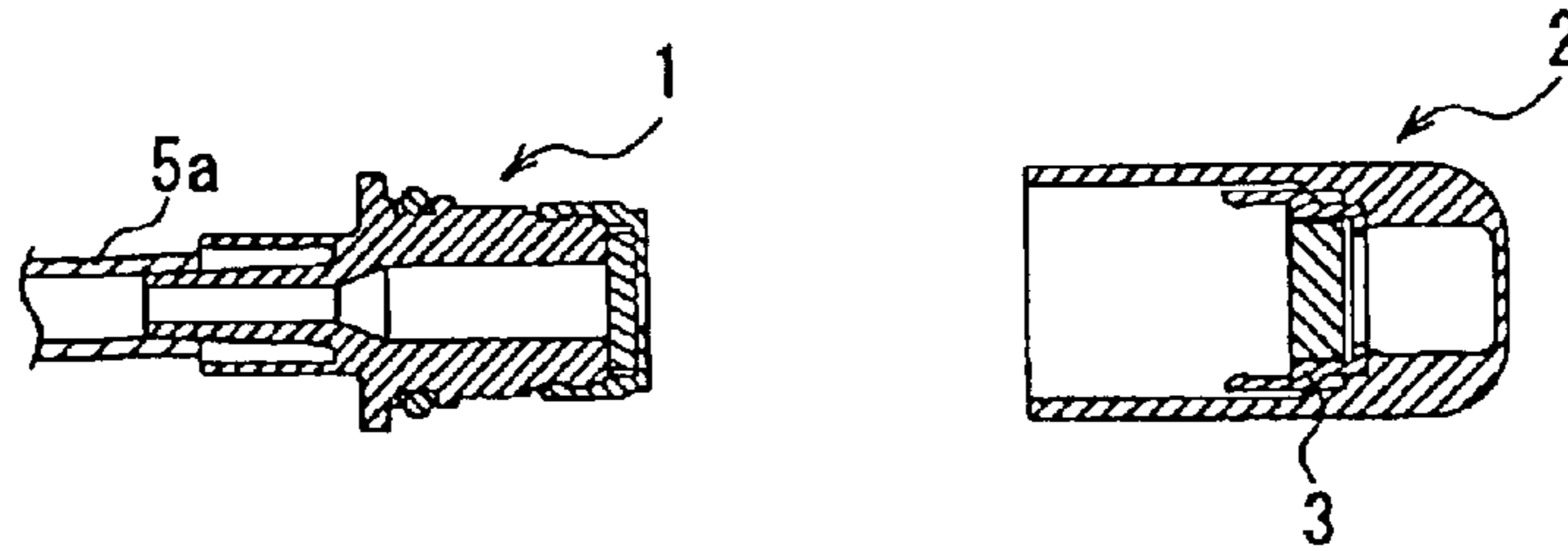


FIG. 1C

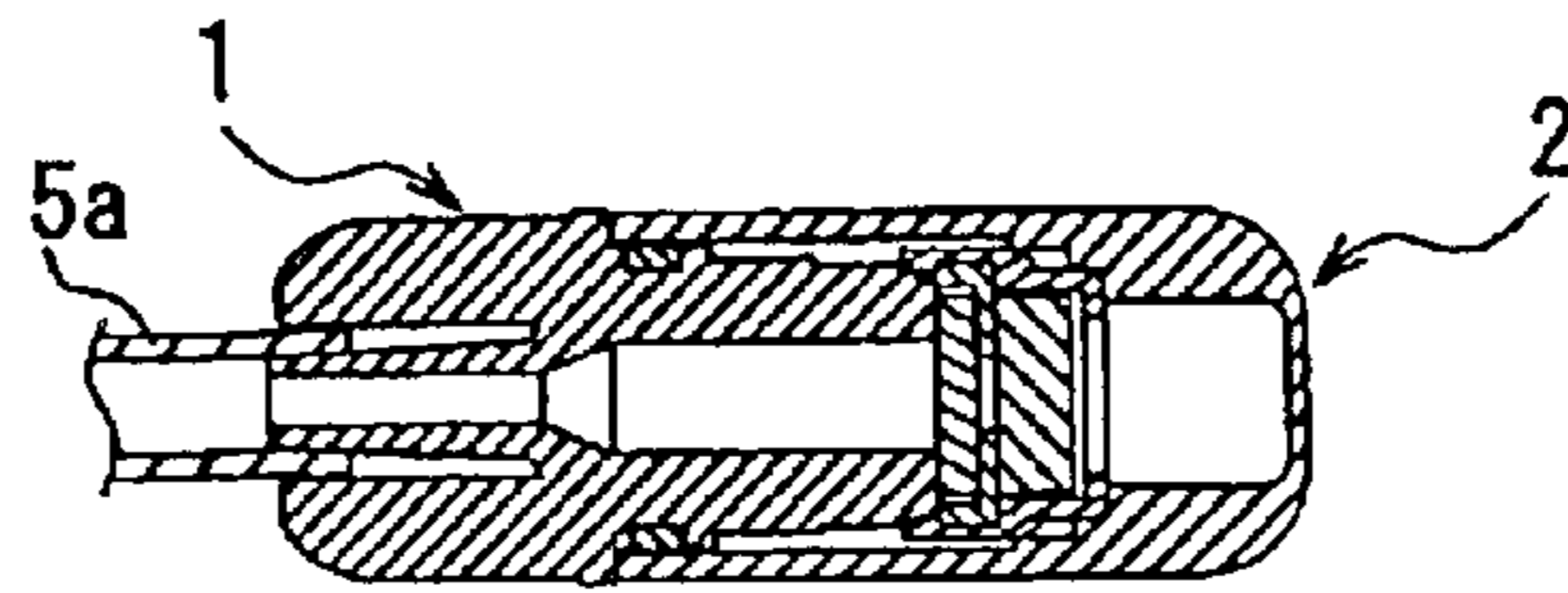


FIG. 1D

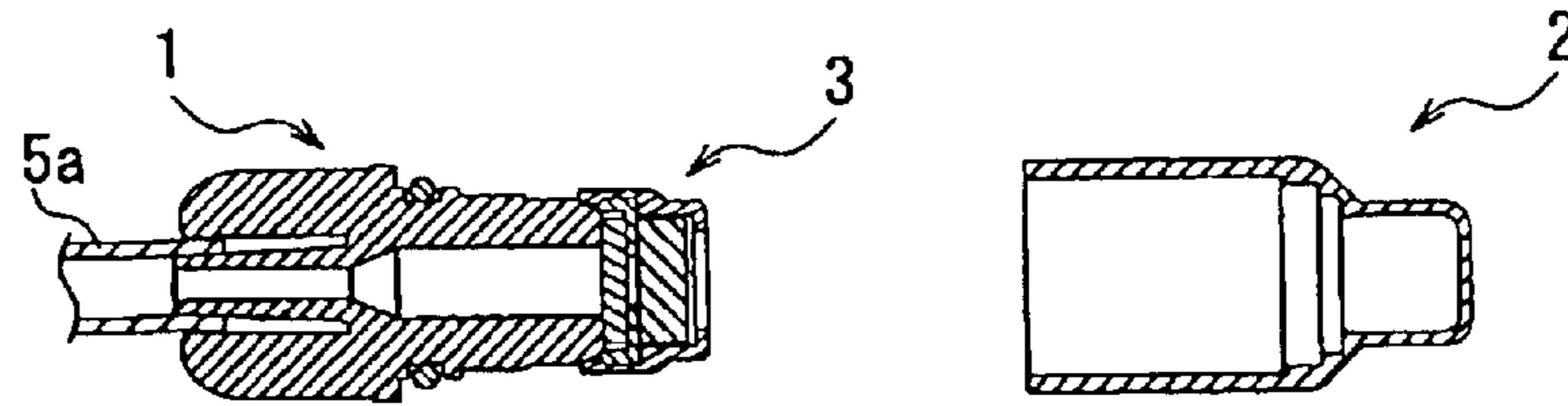


FIG. 1E

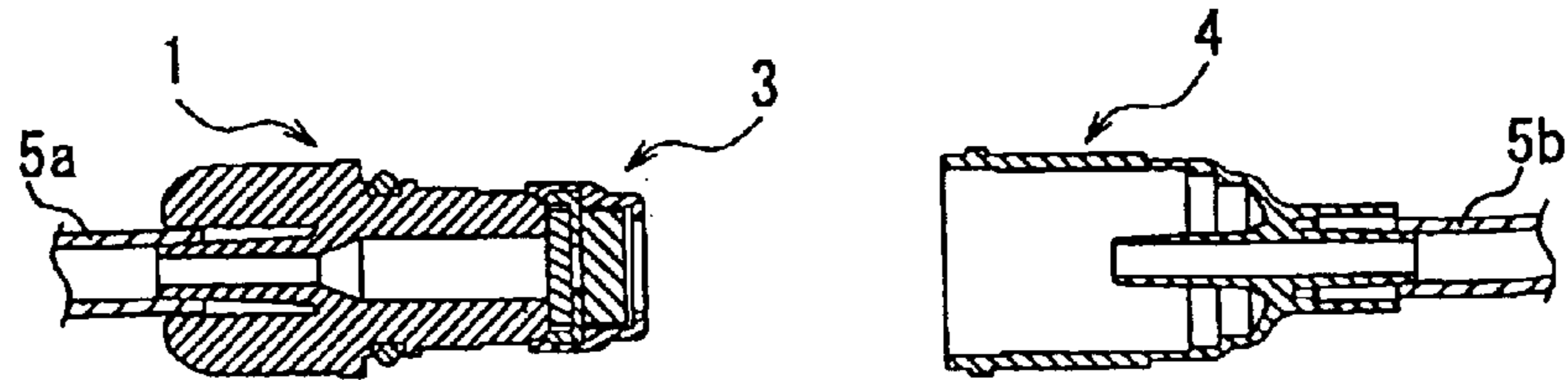


FIG. 1F

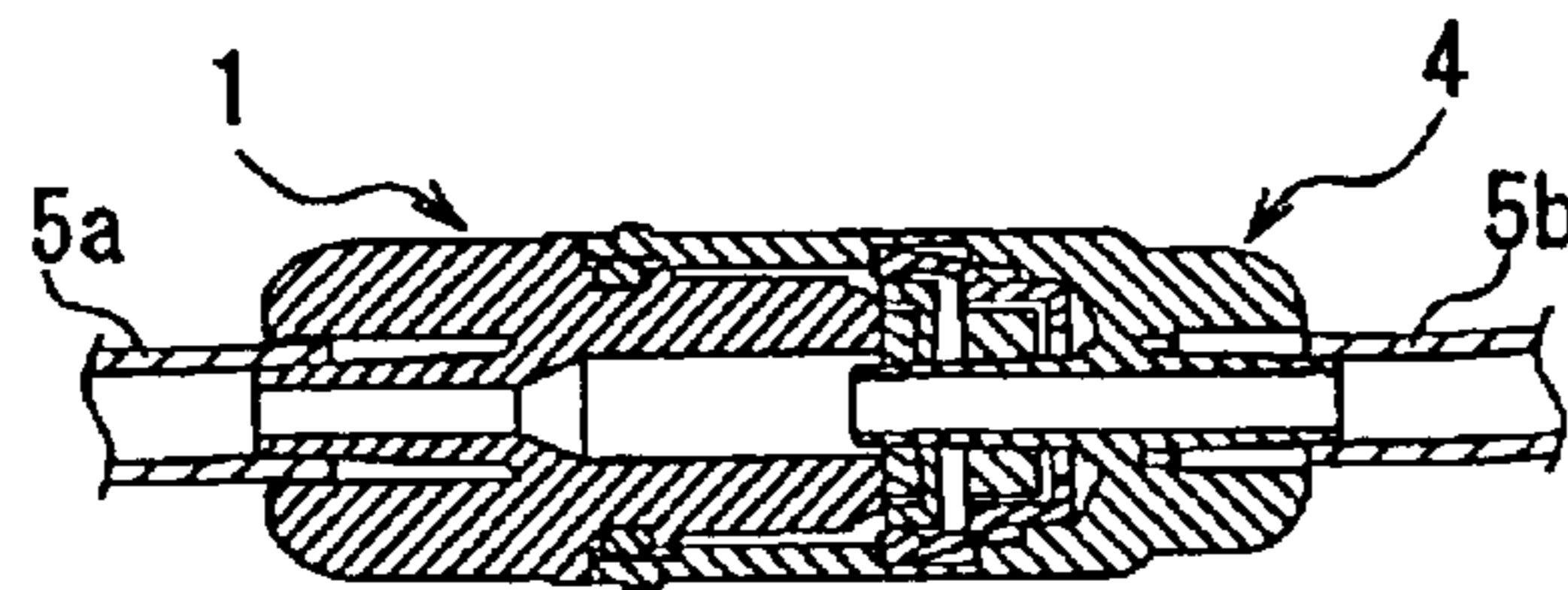
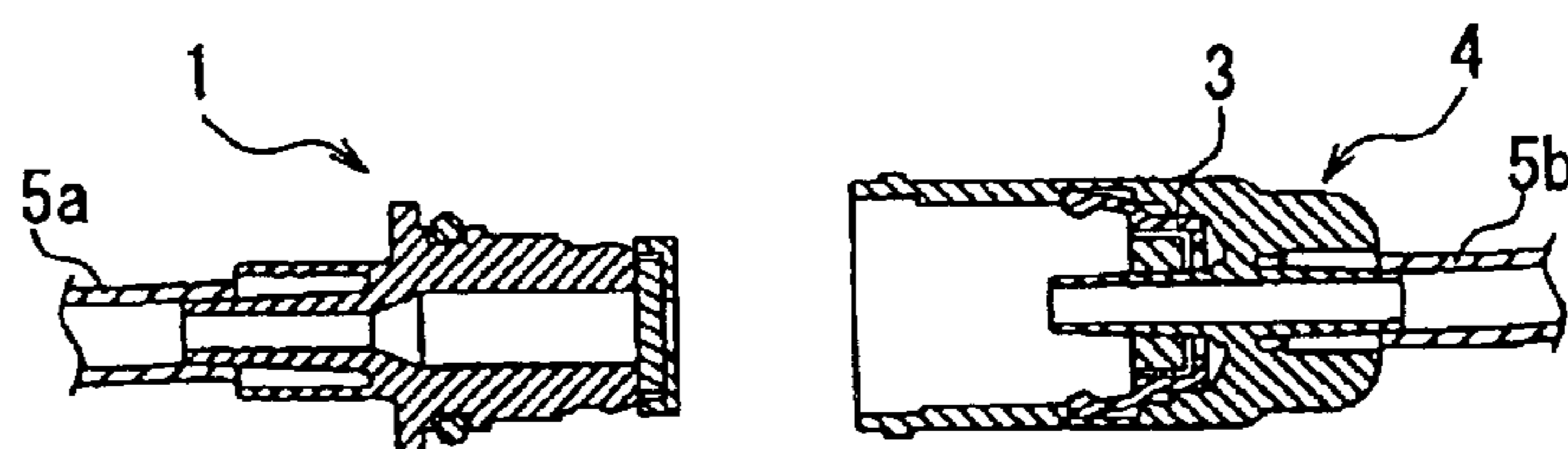


FIG. 1G



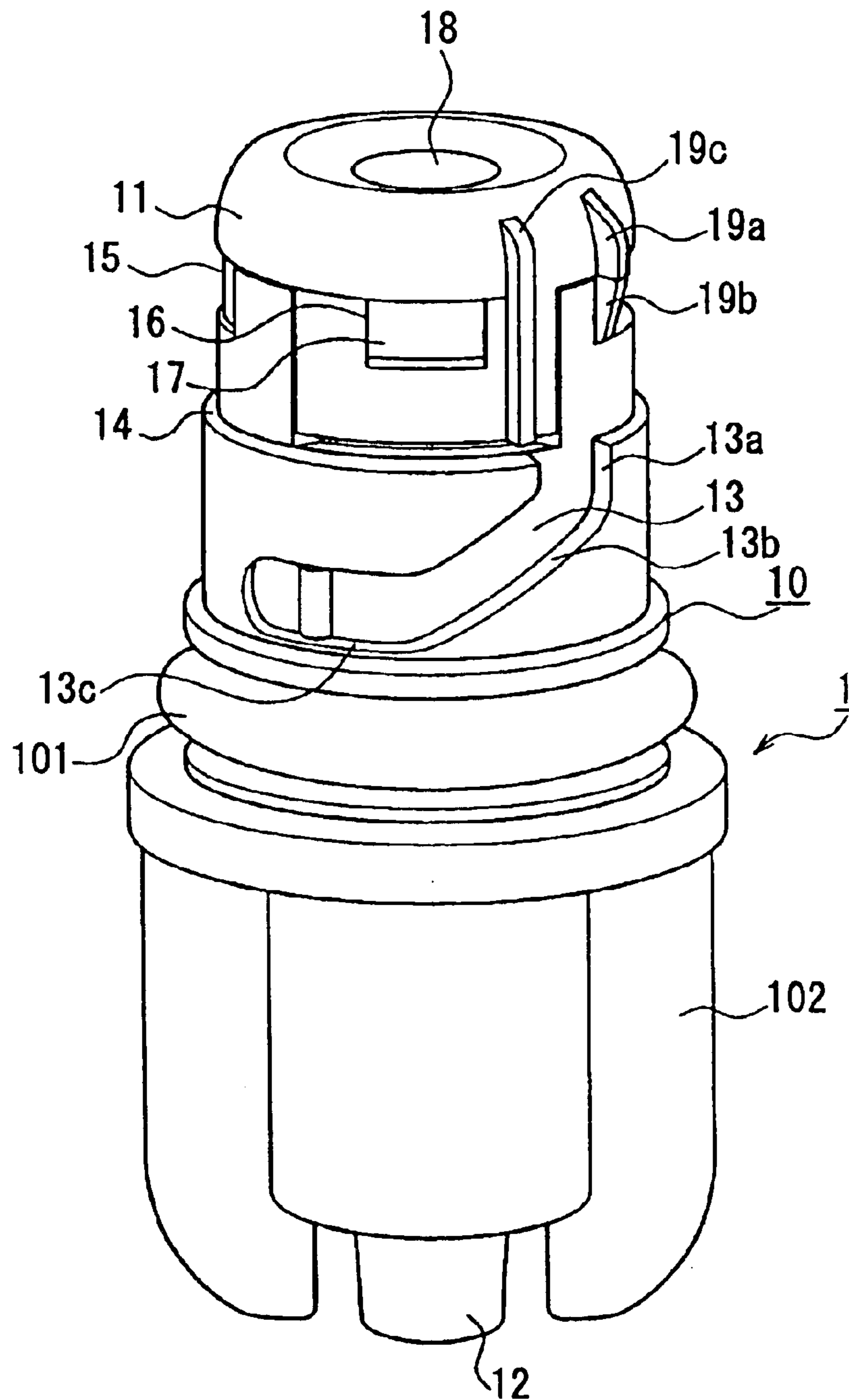


FIG. 2

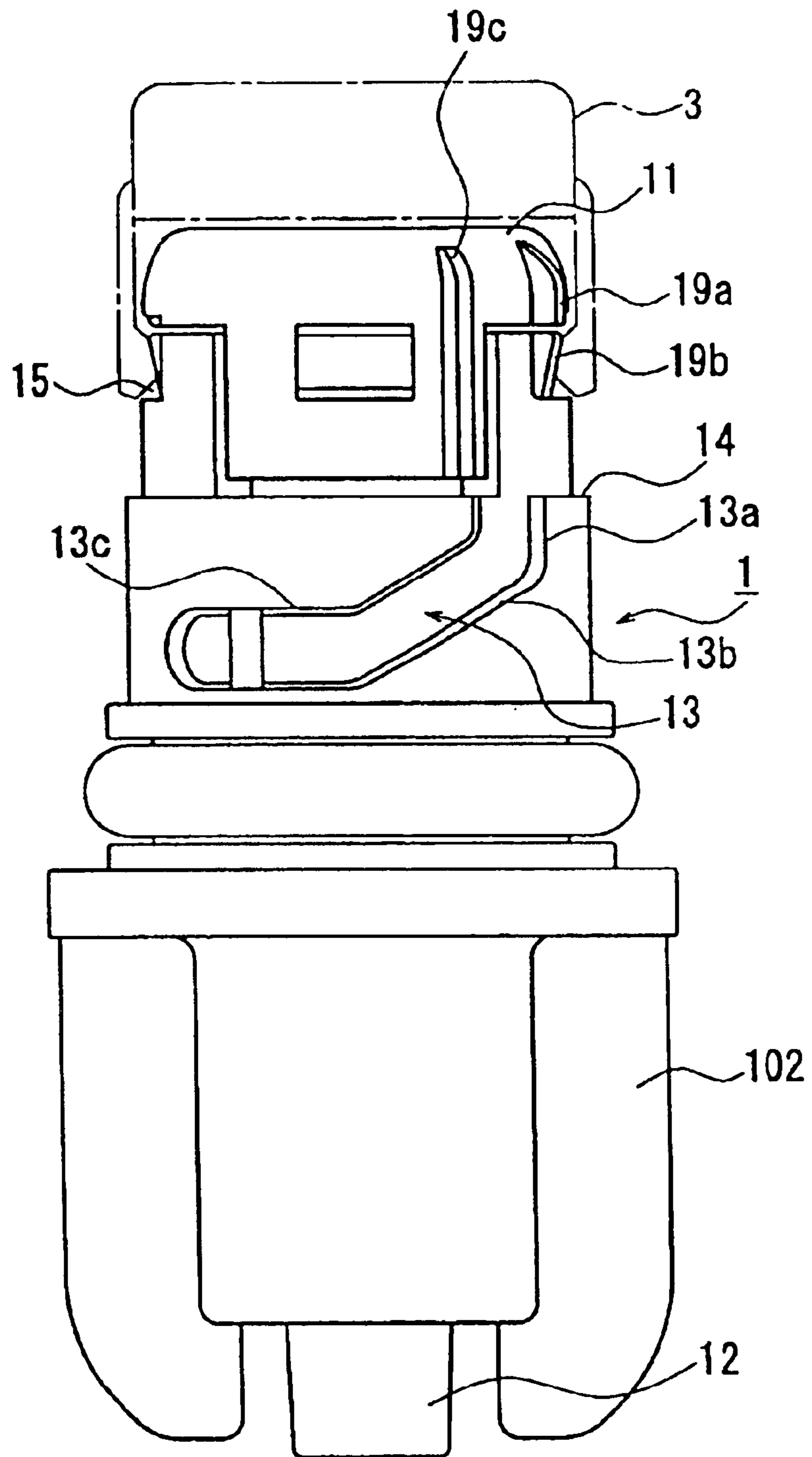


FIG. 3

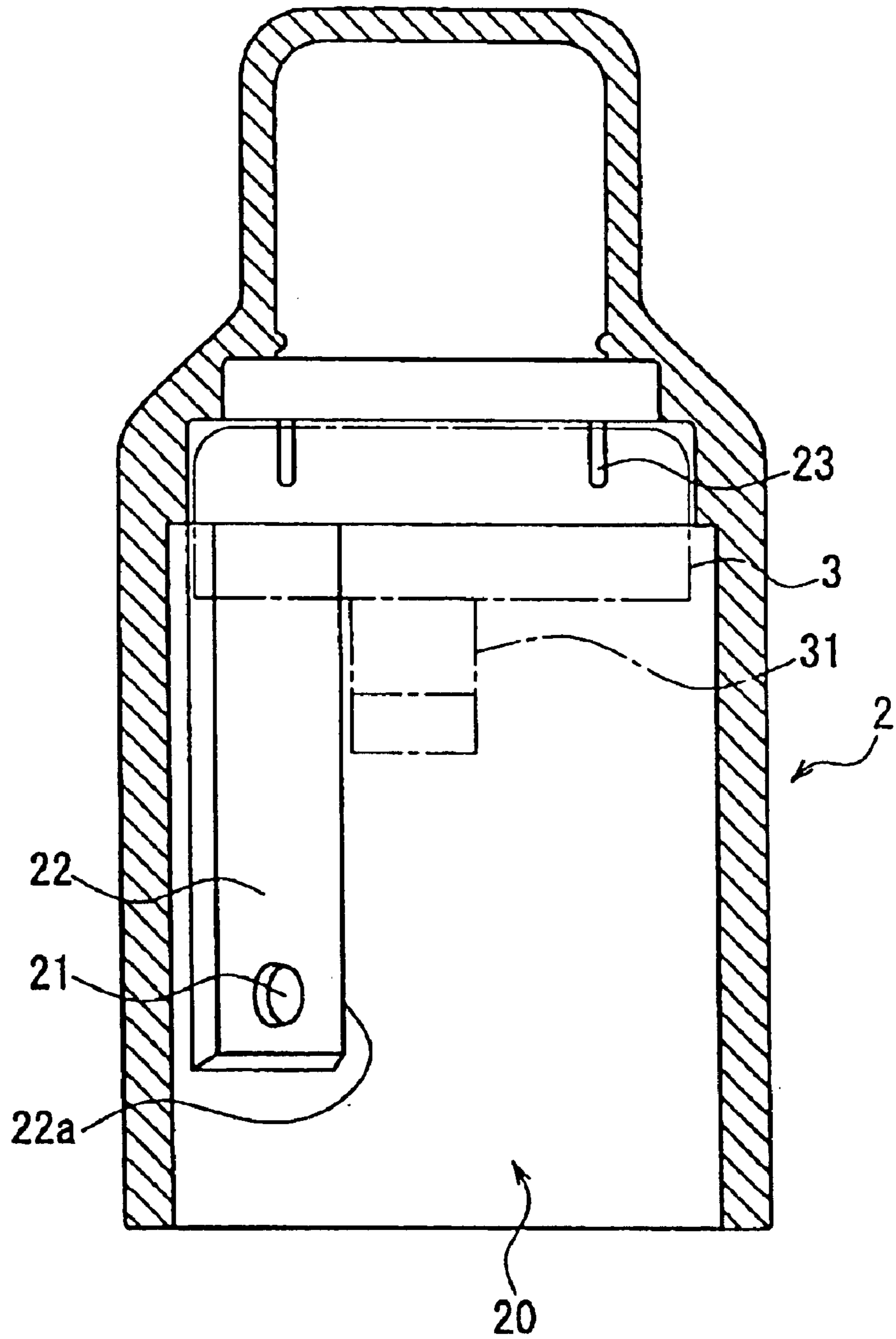


FIG. 4

FIG. 5A

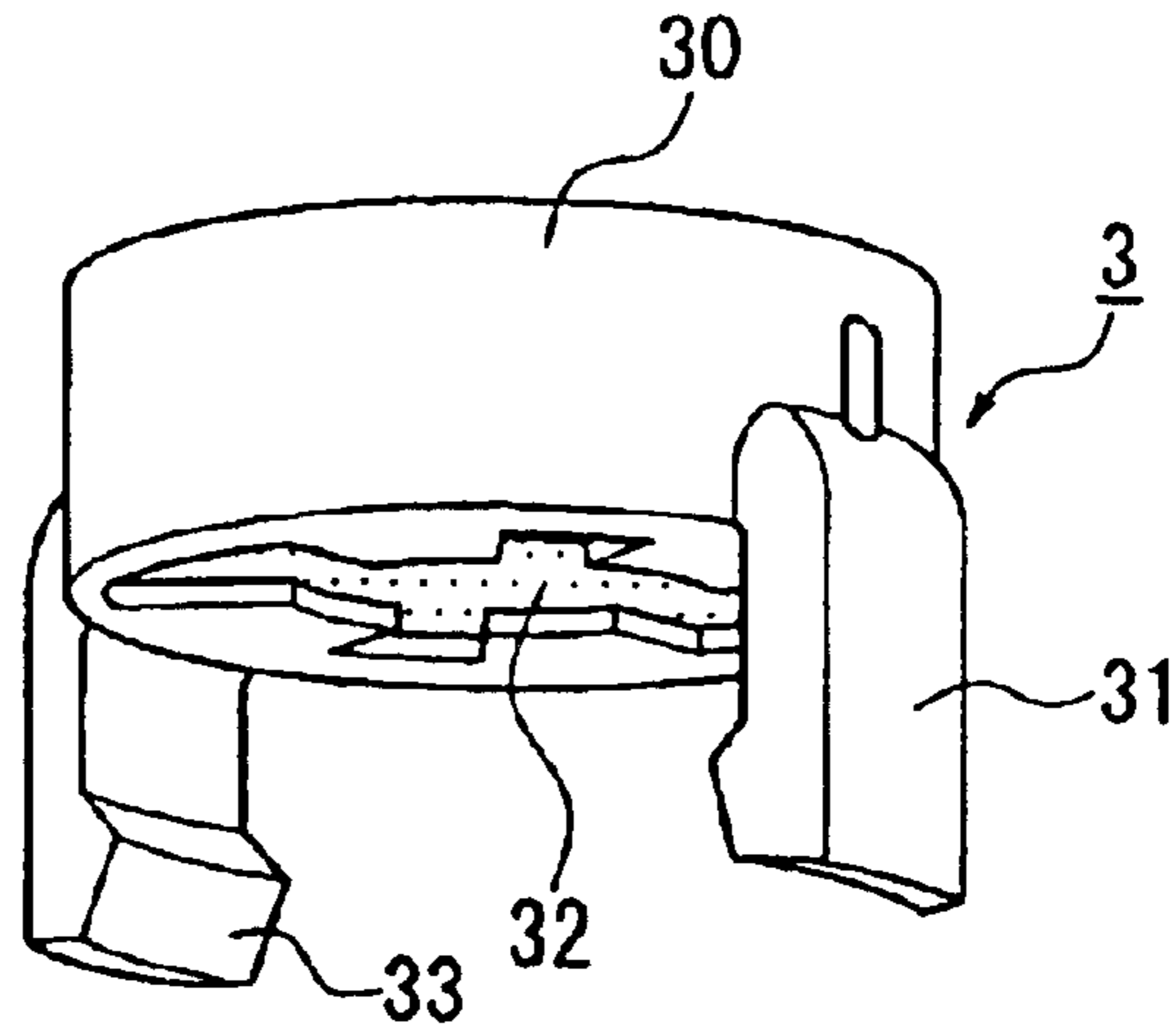


FIG. 5B

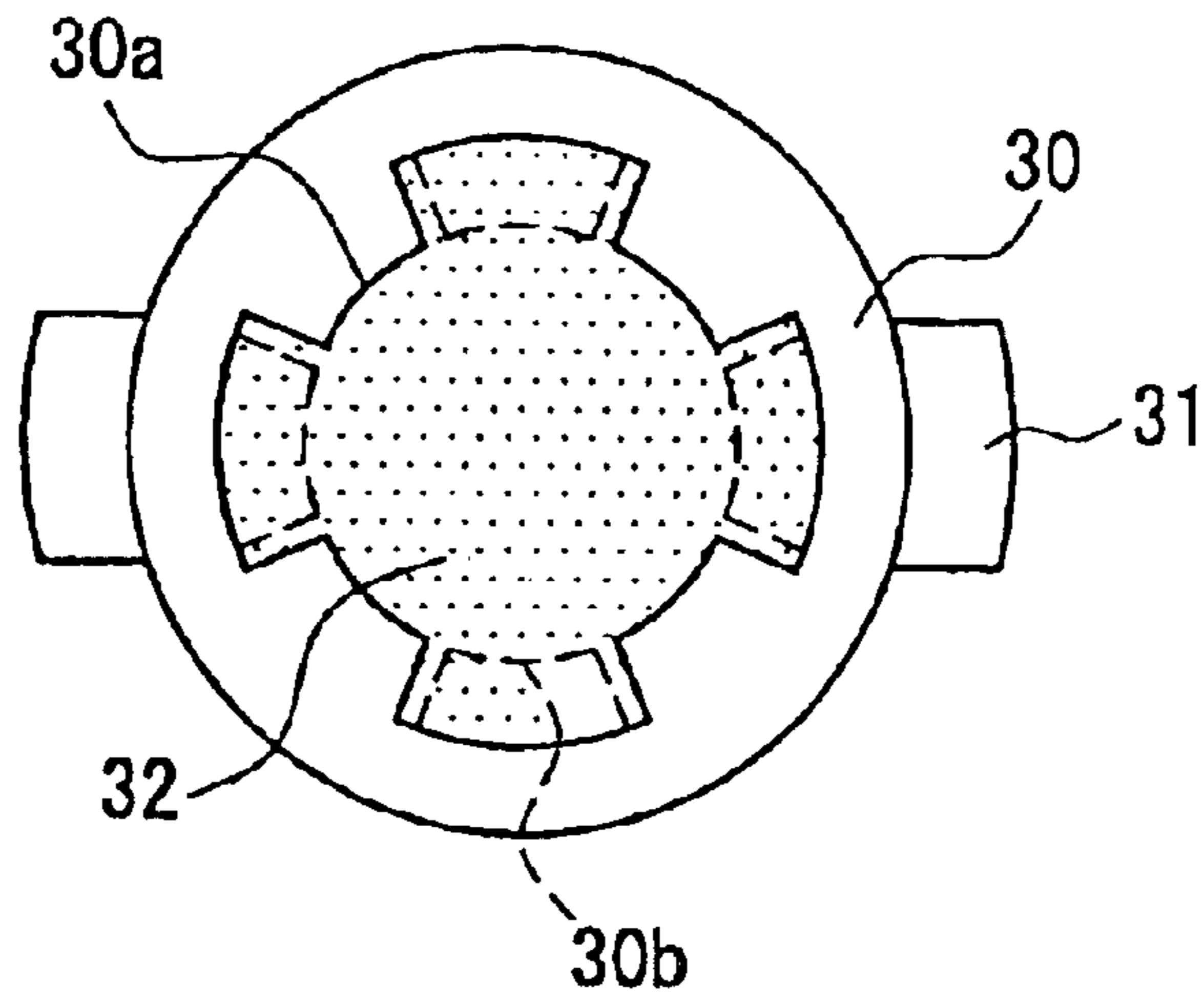
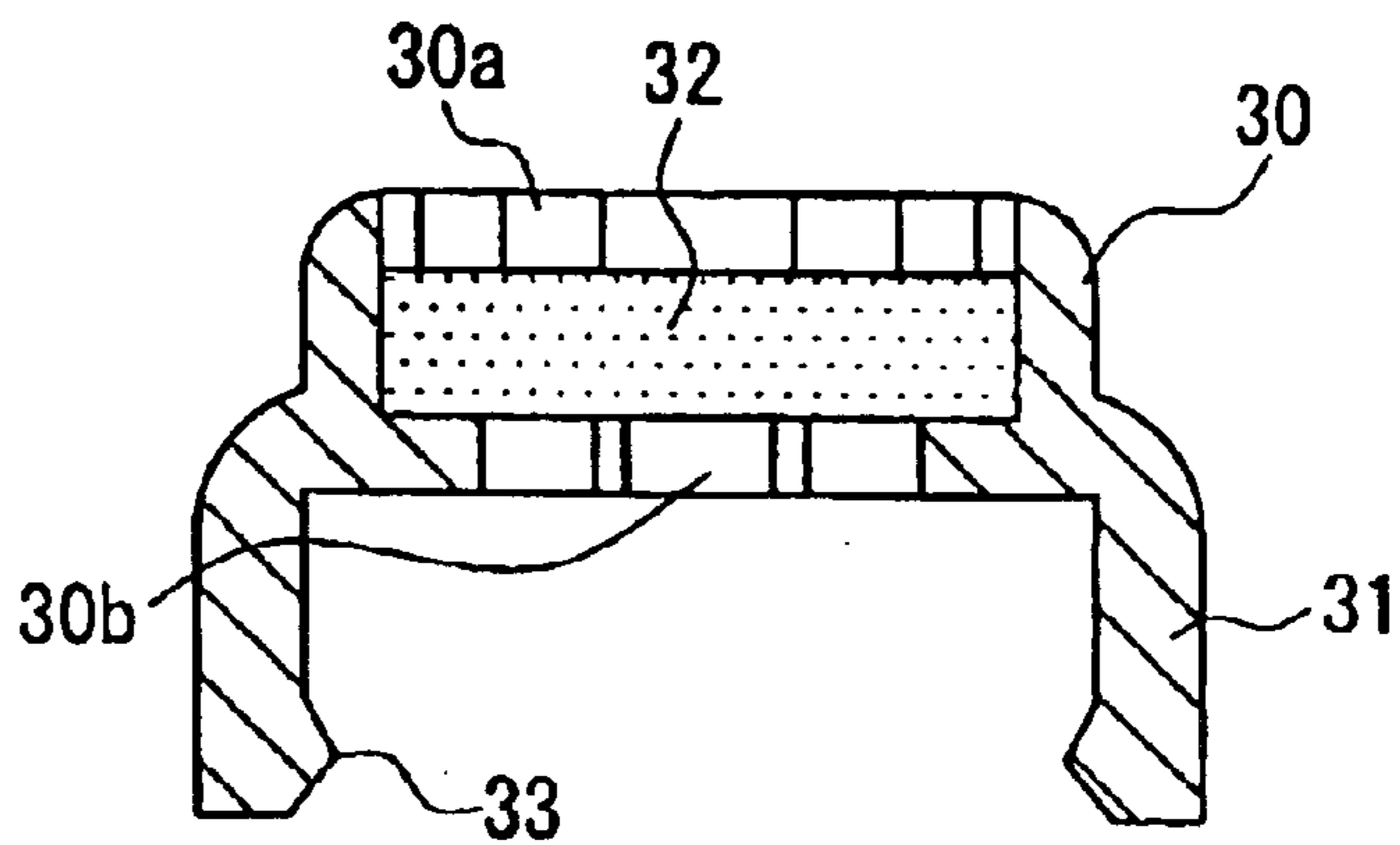


FIG. 5C



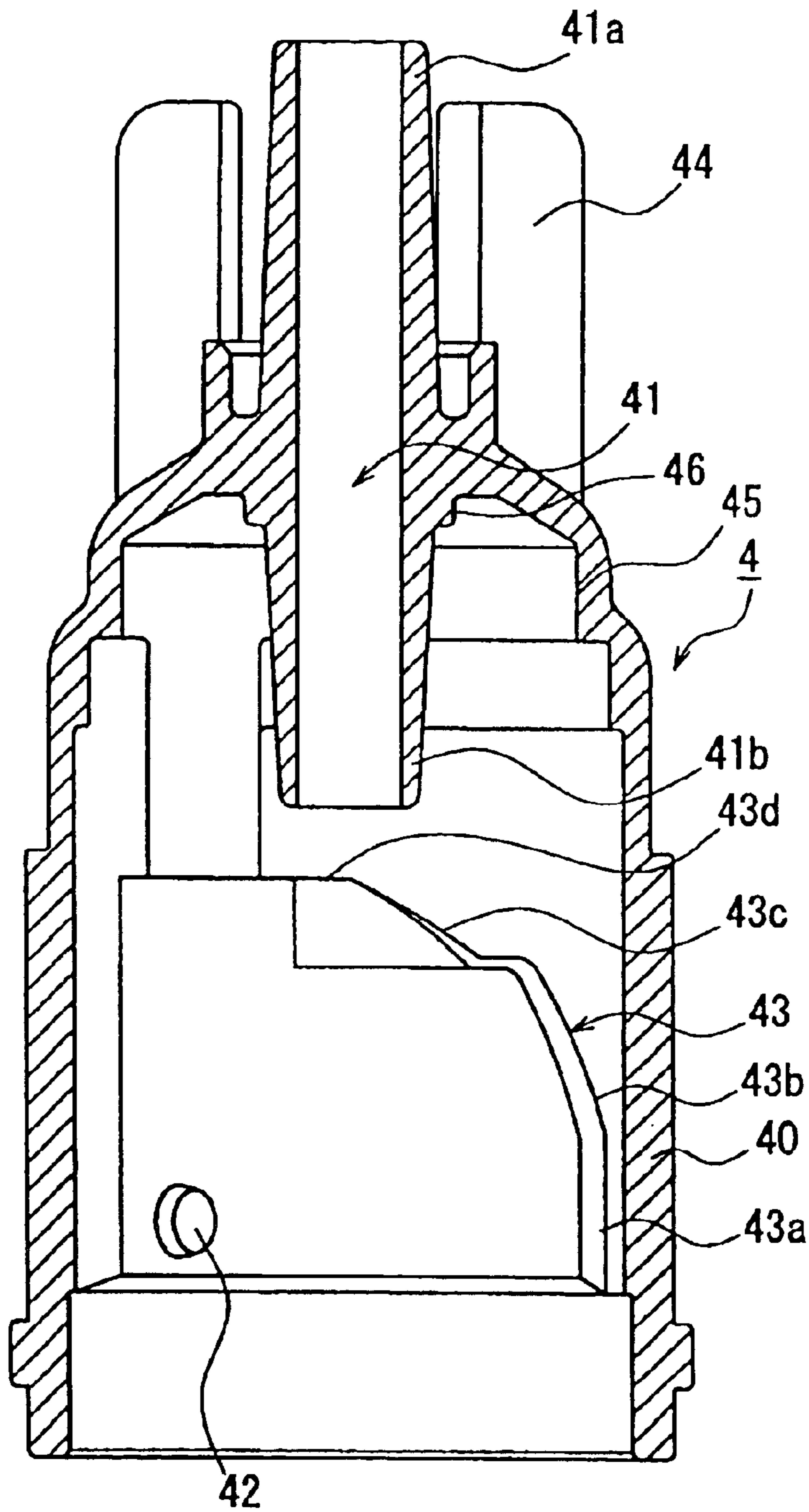


FIG. 6

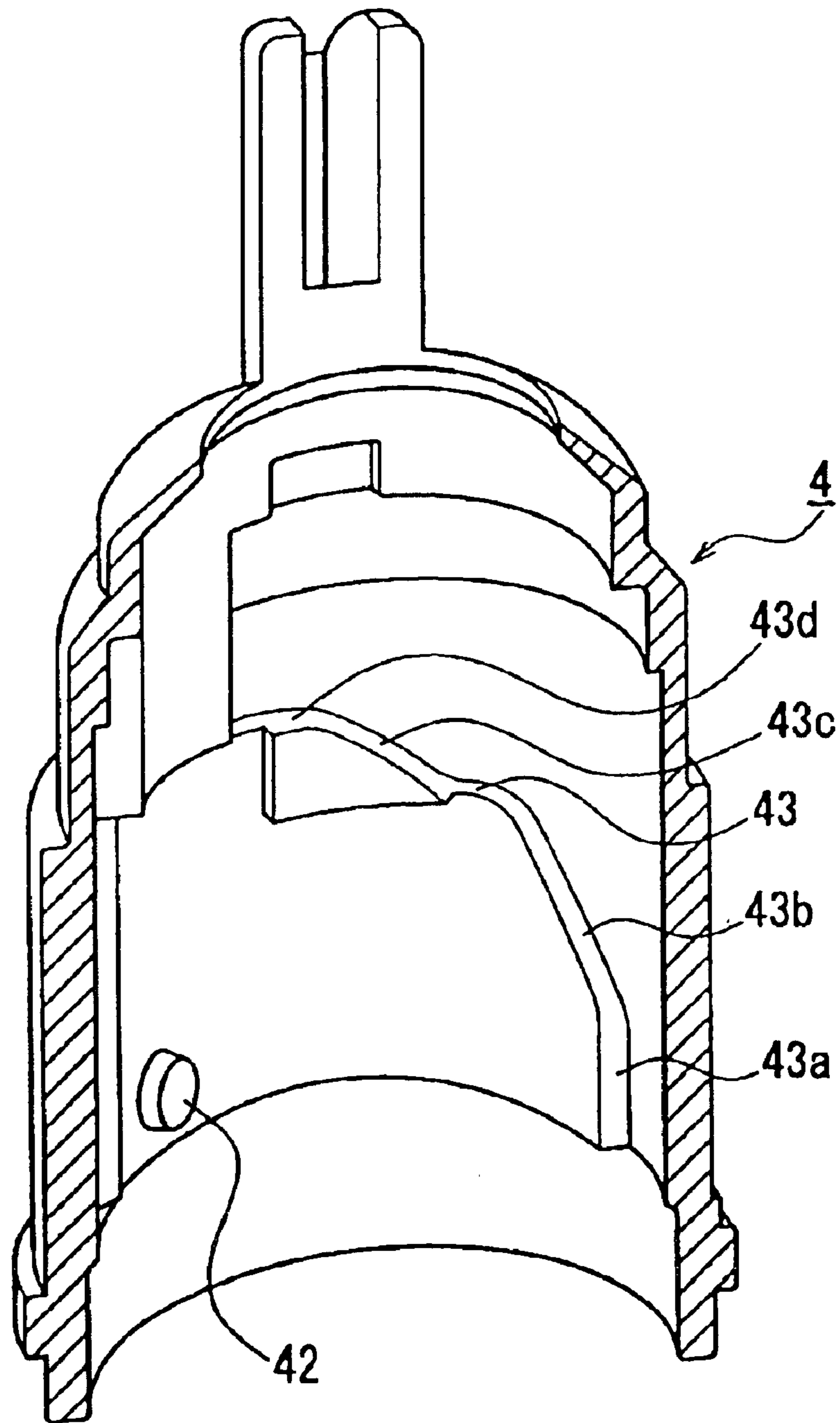


FIG. 7

FIG. 8A

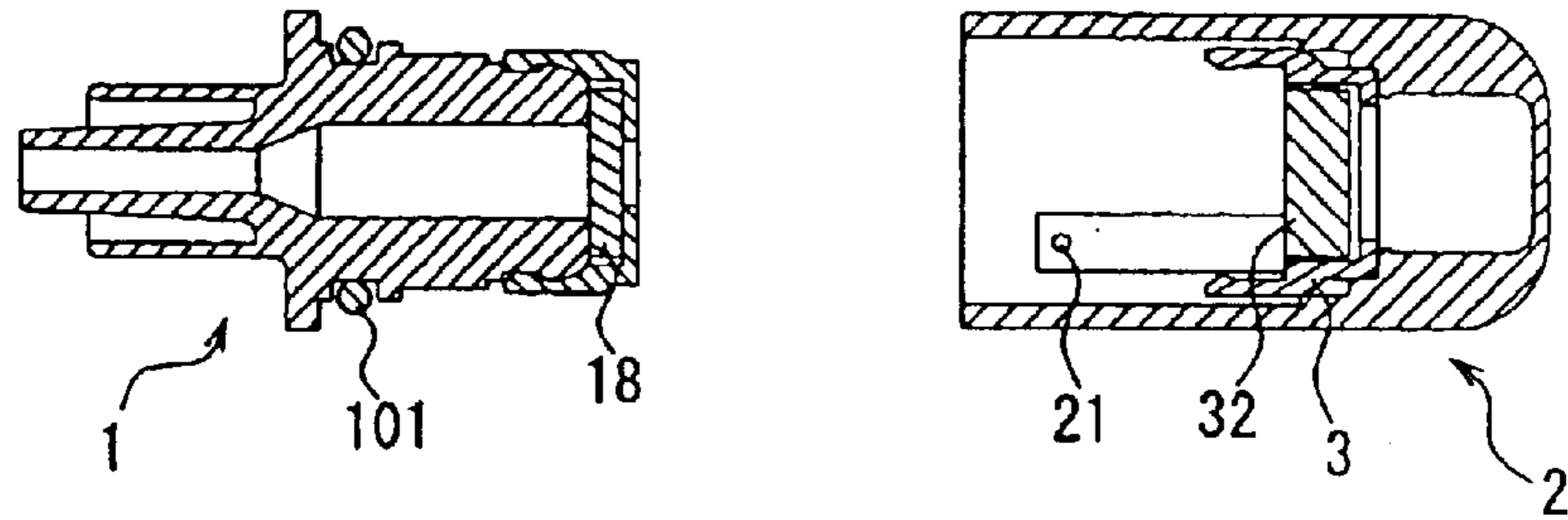


FIG. 8B

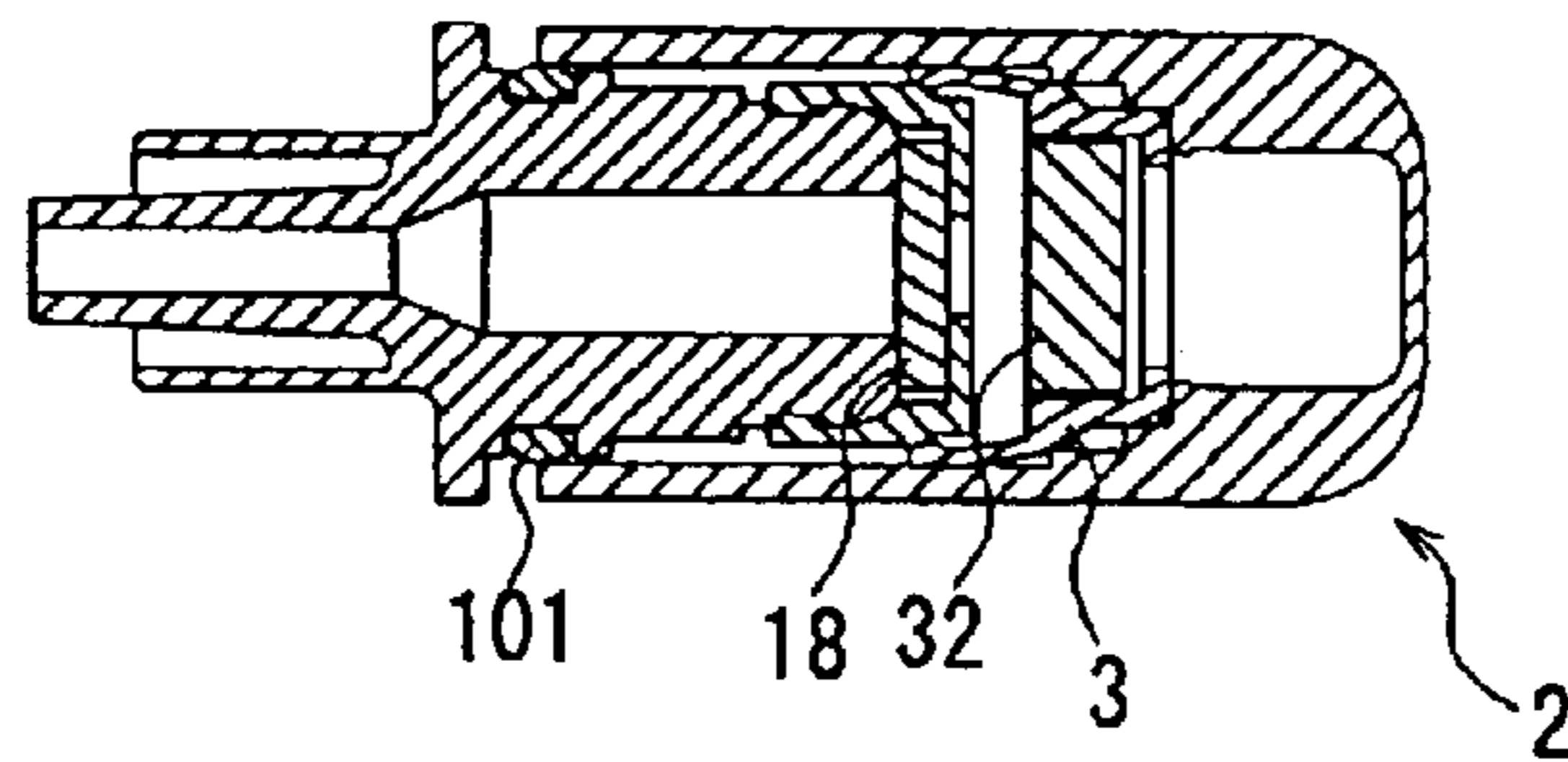


FIG. 8C

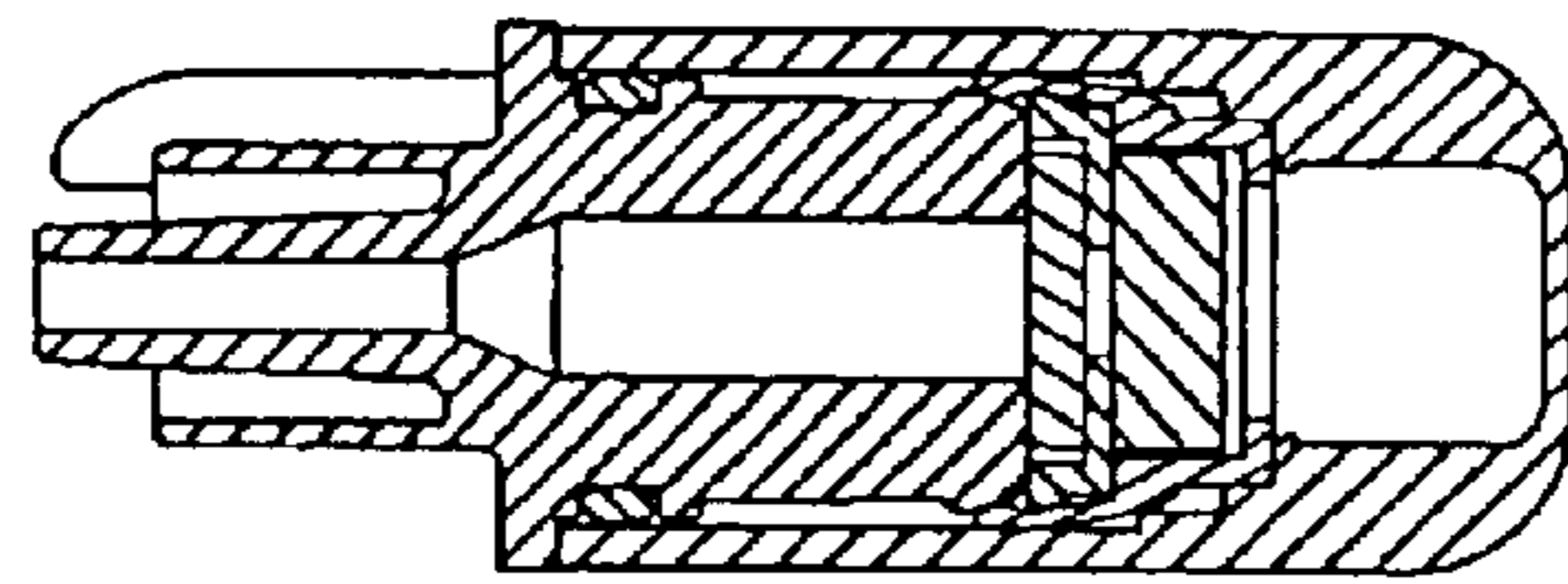


FIG. 8D

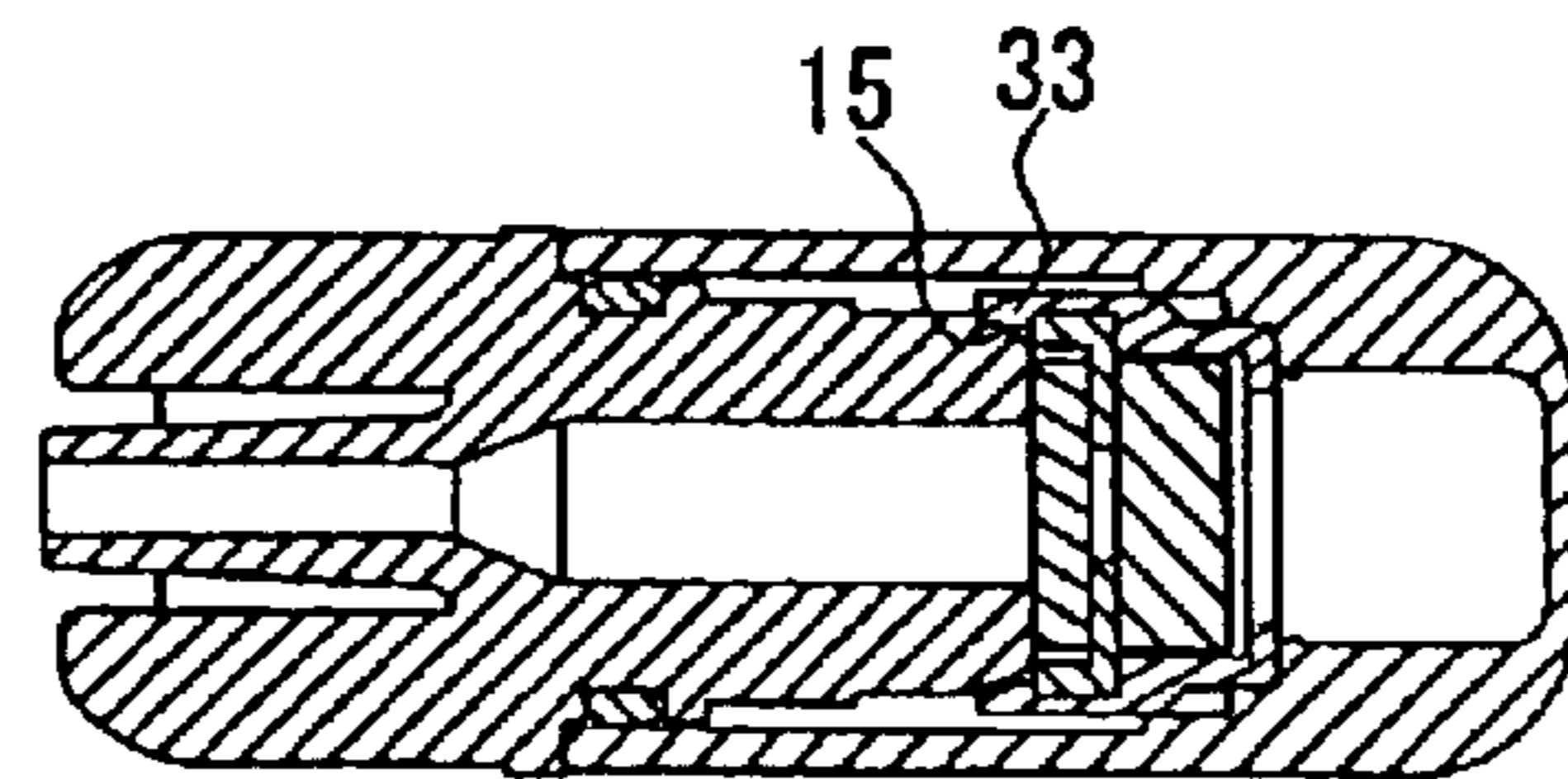
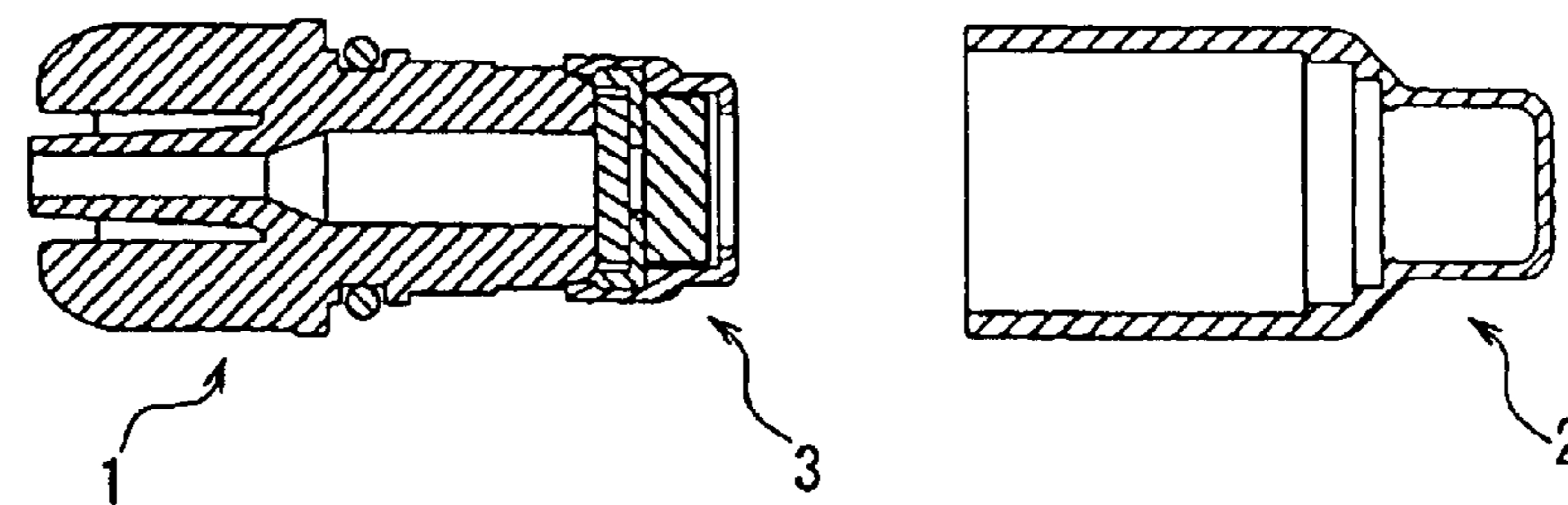
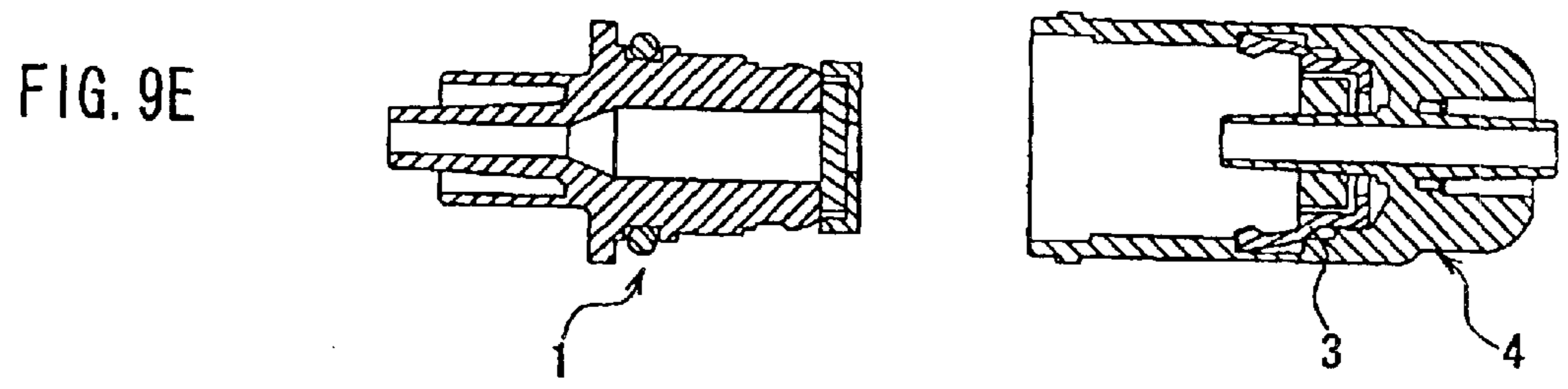
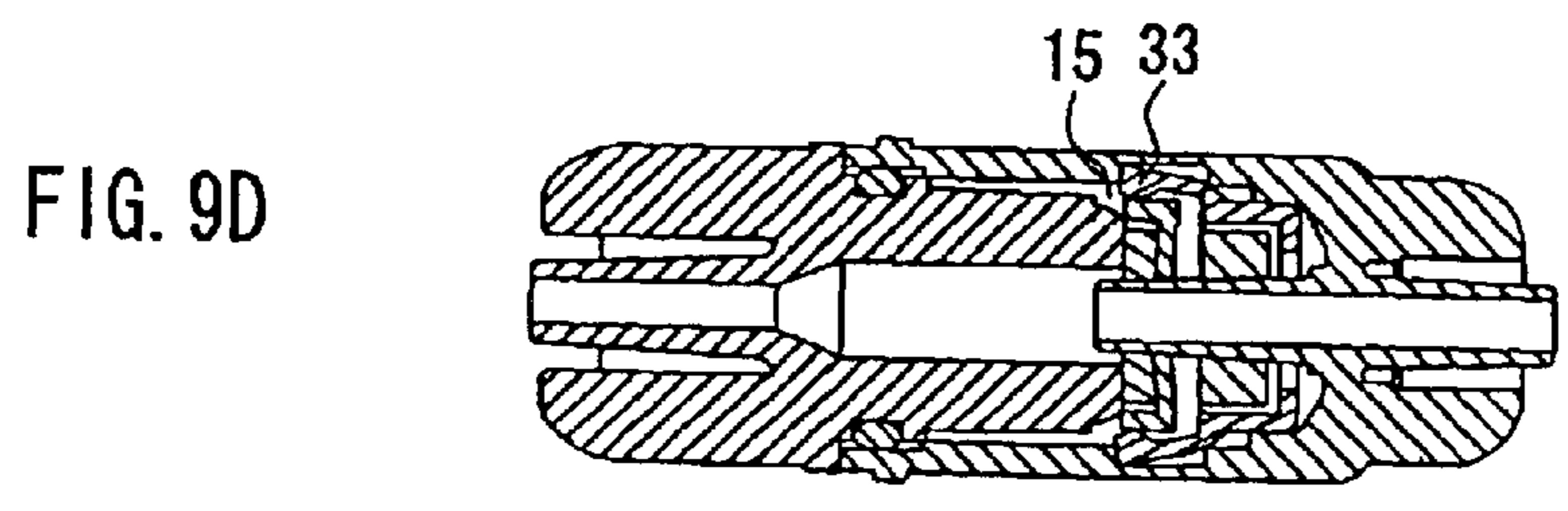
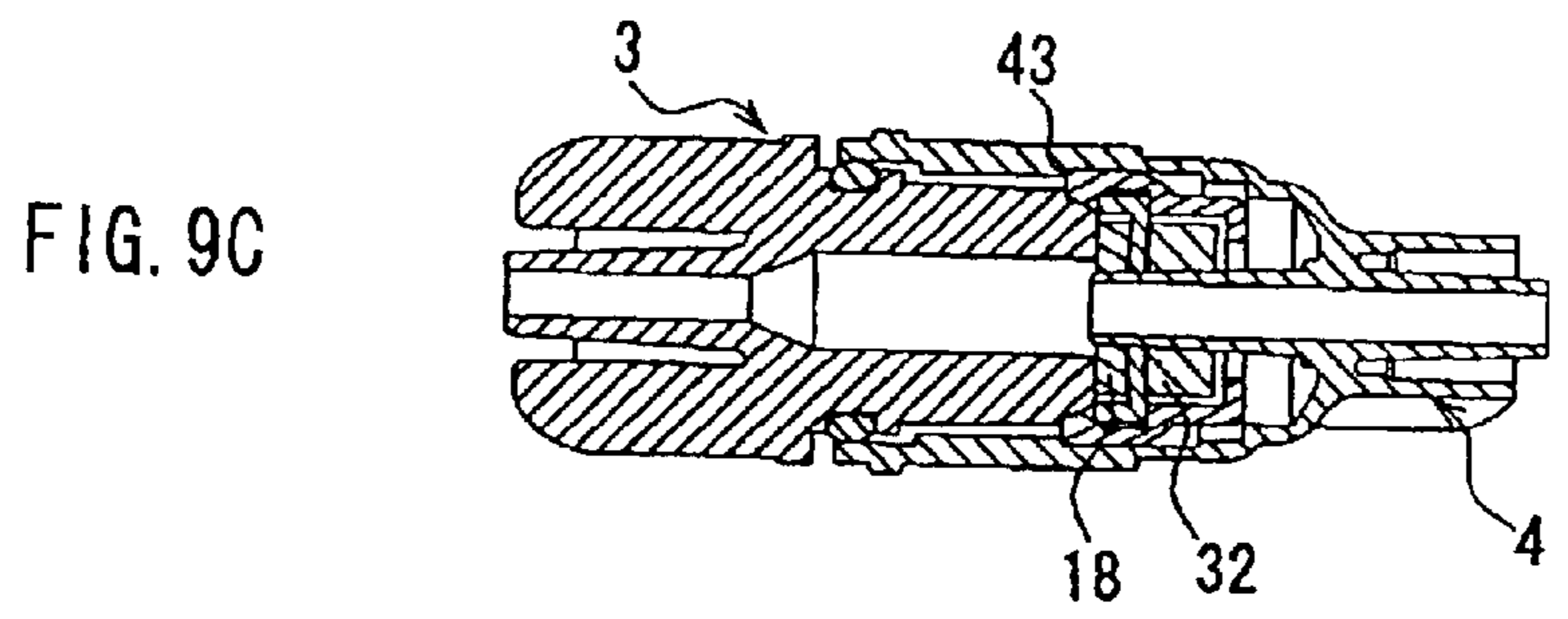
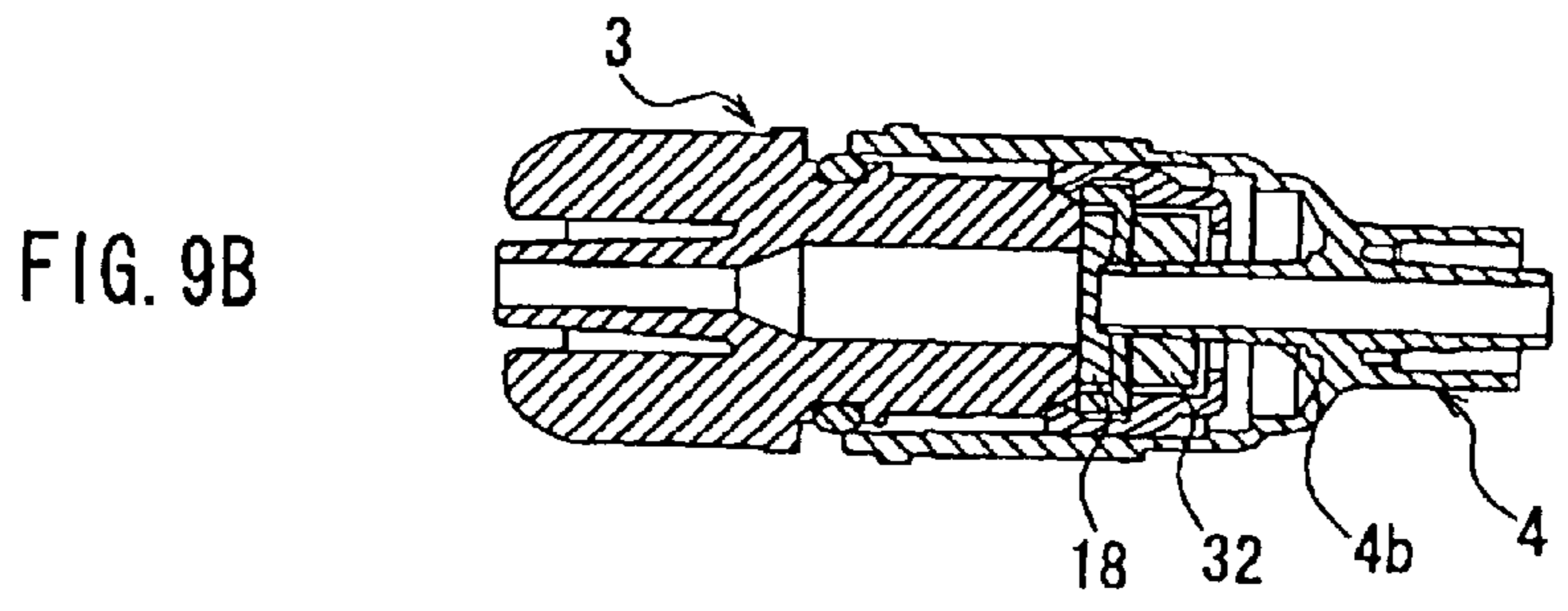
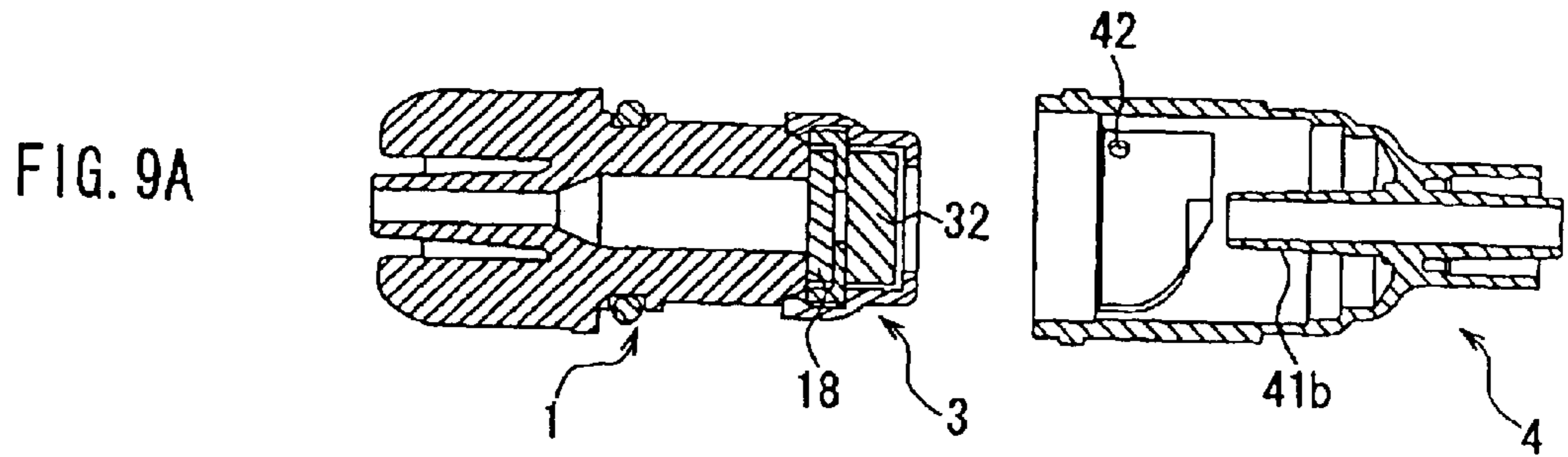


FIG. 8E





CONNECTOR SYSTEM FOR STERILE CONNECTION

This application is a continuation-in-part of U.S. application Ser. No. 10/353,112, filed Jan. 27, 2003, which is incorporated herein in its entirety.

BACKGROUND OF THE INVENTION

1. Field of the Invention

The present invention relates to a connector system, particularly to a system for sterile connection, e.g. as part of a system for conveying fluids to or from a patient. This is useful, for example, for connecting a patient side transfer tube (extension tube) with a container of dialysis solution when a dialysis solution for peritoneal dialysis is exchanged. More particularly, the present invention relates to a connector system for sterile connection provided with a function of securely disinfecting a connecting portion with a simple operation when the connecting and detaching are repeated.

2. Related Background Art

Peritoneal dialysis is a medical treatment method in which a dialysis solution is stored in a patient's abdominal cavity by way of a peritoneal catheter that is implanted surgically in the patient's abdominal cavity beforehand, so that impurities accumulated in the body are filtered using capillary vessels in the peritoneum. The patient undertakes daily activities while a transfer tube (extension tube), which is used continuously for a half year, is connected to the end of the catheter. Then the patient himself connects a bag containing a dialysis solution with a front end of the transfer tube four times per day to exchange the dialysis solution in the abdominal cavity.

The most serious problem to be addressed for carrying out the peritoneal dialysis is bacteria in the air or attached to the skin mistakenly entering into the abdominal cavity during the operation of exchanging the dialysis solution as required four times per day. If bacteria enter into the abdominal cavity, these bacteria cause inflammation of the peritoneum to develop peritonitis. As a result, for treating the peritonitis, the catheter might be extracted in bad cases, which leads to a situation incapable of continuing the peritoneal dialysis. Furthermore, the peritonitis repeated for a long term degrades the function of a peritoneum, and as a result, sufficient efficiencies of the dialysis cannot be obtained, or the patient might suffer from sclerosing encapsulating peritonitis (SEP) that is intractable and leads to bad prognosis, including possible death.

Thus, in the peritoneal dialysis, it is important, when the dialysis solution is exchanged, to reduce the contamination by bacteria of a connector that connects a transfer tube and a container of dialysis solution. Conventionally, products for connecting tubes by melting with a heated copper plate or for disinfecting a connecting portion with ultraviolet rays are available commercially for preventing the contamination by bacteria. However, since these products necessarily require units dedicated to the products, a patient always has to carry the unit. Moreover, in the event of problems with the unit, serious problems might occur.

Meanwhile, in connection methods that do not use such units, a male and female screw type connector still is utilized. In these methods, since a channel for the dialysis solution necessarily becomes open in the connecting operation, it is virtually impossible to prevent the contamination by bacteria.

As for connecting members that do not require units and can prevent the contamination by bacteria, various structures

have been examined until now. Examples of those ideas are a structure using a septum, which is pushed open to realize the fitting for connection, a structure where a lid member is opened and closed automatically when connectors are fitted, and a structure where fitting is realized by breaking a film covering a connecting portion.

However, all of those structures have problems in that their mechanism becomes complicated, their size becomes large and the required functions cannot be obtained sufficiently, and therefore none of them have been put into practical use.

SUMMARY OF THE INVENTION

Therefore, with the foregoing in mind, it is an object of the present invention to provide a connector system for sterile connection that enables connection with a simple operation for avoiding the contamination by bacteria, without substantially increasing the size of the conventional connectors.

The connector system for sterile connection of the present invention includes: a male type connector including a tube connecting portion at a rear end portion thereof; a protective cap having a substantially cylindrical shape with a closed first end and being capable of connecting and disconnecting with/from a front end side of the male type connector; an inner cap including a ring-shaped portion that supports a disinfectant-impregnated member therein, the inner cap being retained inside the protective cap in an initial state; and a female type having a double-cylinder structure in which an inner cylinder is fixed at one end portion of an outer cylinder, the inner cylinder including an internal end portion located inside the outer cylinder and an external end portion exposed outside the outer cylinder and capable of connecting with a tube. In the example of a peritoneal dialysis system, the male type connector may be the patient side, the female type connector may be the circuit side, and the external end portion of the inner cylinder of the circuit side connector may be capable of connecting with a front end of a circuit in a container of dialysis solution. A channel for solution is connected by fitting the outer cylinder of the female type connector with the male type connector. When the protective cap is fitted with the male type connector, the inner cap assumes a state of being retained at the front end side of the male type connector. When the protective cap is removed from the male type connector, the inner cap is detached from the protective cap because of a retaining force at the front end side of the male type connector. When the male type connector with the inner cap retained at the front end thereof is connected with the female type connector, the internal end portion of the inner cylinder penetrates through the disinfectant-impregnated member in the inner cap, so that the channel is opened. When the connection between the male type connector and the female type connector is released, the inner cap is retained inside the female type connector and is detached from the front end of the male type connector.

With this configuration, the front end portion of the male type connector continues to be disinfected by the disinfectant-impregnated member in the inner cap. In addition, when connecting with the circuit side connector, the inner cylinder of the female type connector also is disinfected by the disinfectant-impregnated member, so that bacteria do not intrude into the channel. Furthermore, every time the dialysis solution is exchanged, the inner cap is exchanged automatically into a new one, and therefore this system always is disinfected by a new disinfectant-impregnated member without a complicated procedure.

Preferably, the male type connector includes a septum member at a front end portion thereof for protecting the channel, and when the male type connector with the inner cap retained at the front end thereof is connected with the female type connector, the internal end portion of the inner cylinder penetrates through the disinfectant-impregnated member in the inner cap and the septum member of the male type connector, so that the channel is opened.

Preferably, the inner cap includes a plurality of engaging legs extending from an outer edge portion of the ring-shaped portion in a direction along an axis of the ring. An engaging convexity is formed at a front end of each of the engaging legs so as to protrude inward. Engaging concavities are formed on an outer surface of the front end portion of the patient side connector so as to allow engagement with the engaging convexities formed at the engaging legs of the inner cap. An inner cap retaining portion is formed on an inner wall inside the protective cap, where a retaining force exerted by the engagement between the engaging convexity of the inner cap and the engaging concavity of the male type connector is larger than a force exerted by the inner cap retaining portion of the protective cap to retain the inner cap. When the protective cap with the inner cap retained therein is fitted with the male type connector, the engaging convexities of the inner cap engage with the engaging concavities of the male type connector, and when the protective cap is removed from the male type connector, the retaining of the inner cap by the inner cap retaining portion of the protective cap is released due to the retaining of the inner cap at the engaging concavities of the patient side connector, so that the inner cap is detached from the protective cap while being fitted with the front end of the male type connector.

In the above configuration, preferably, on the outer surface of the patient side connector, a circumferential step portion extending in a circumferential direction is formed so that a diameter at the front end side of the male type connector is smaller than that at a base end side, and a guide groove is formed so as to extend from the circumferential step portion toward the base end. The guide groove includes an inclined portion that is inclined with respect to an axis of the male type connector. On the inner wall close to an opening end portion of the protective cap, a guide protrusion is formed, and on the inner wall and extending toward the closed end side of the protective cap, a rotation blocking step portion is formed, the rotation blocking step portion being capable of contacting with the engaging legs of the inner cap so as to block a rotational action of the inner cap. When the male type connector is inserted into an opening of the protective cap with the guide protrusion of the protective cap facing the guide groove of the male type connector, and then the protective cap and the male type connector are rotated while being urged axially toward each other, the guide protrusion slides along the guide groove, so that the male type connector is pulled into an inside of the protective cap by a driving force resulting from a screw action by the inclined portion of the guide groove, and the engaging convexities of the inner cap, whose rotation is blocked by the rotation blocking step portion, engage with the engaging concavities of the male type connector.

In the above configuration, preferably, the male type connector includes a blocking wall at the front end portion thereof, which is capable of contacting with a side face portion of the engaging leg of the inner cap when the inner cap is fitted thereto. The outer cylinder of the female type connector includes: a guide protrusion formed on an inner wall close to an open end portion thereof, the guide protrusion being formed to correspond to the guide protrusion of

the protective cap; a guide step portion including an inclined portion that is inclined with respect to an axis of the female type connector; and an inner cap retaining portion formed at an inside of the connector and being capable of retaining the inner cap. When the male type connector with the inner cap retained therein is inserted into the opening of the female type connector with the guide protrusion of the outer cylinder facing the guide groove of the male type connector, and then the female type connector and the male type connector are rotated while being urged axially toward each other, the guide protrusion slides along the guide groove, so that the male type connector is pulled into the inside of the female type connector by a driving force resulting from a screw action by the inclined portion of the guide groove. At the same time the front ends of the engaging legs of the inner cap slide along the inclined portion of the guide step portion of the female type connector while rotation of the inner cap is blocked by the blocking wall of the male type connector, so that a force in the axis direction acts on the inner cap so as to separate the inner cap from the male type connector, resulting in the release of the engagement between the inner cap and the male type connector, and the inner cap assumes a state of being retained by the inner cap retaining portion of the outer cylinder. The two guide protrusions (i.e., of the male type connector and of the protective cap) are formed so that they will act in the same manner and perform a similar function.

In the above configuration, preferably, the inner cap retaining portion of the circuit side connector is configured with a horizontal step portion provided at the innermost of the guide step portion. When the front ends of the engaging legs of the inner cap contact with the horizontal step portion, the inner cap is prevented from moving in the axis direction toward the opening of the outer cylinder so as to be retained in the female type connector.

In the above configuration, preferably, the inner cap retaining portion of the female type connector is configured by setting the dimensions of constituting elements so that at least portions of the inner wall of the inside of the outer cylinder contact with an outer circumferential surface of the ring-shaped portion of the inner cap or so that at least portions of the outer wall of the internal end portion of the inner cylinder contact with an inner circumferential surface of the ring-shaped portion of the inner cap, whereby the inner cap is retained by the thus generated frictional force.

In the above configuration, preferably, the inner cap retaining portion of the protective cap is configured with a convex stripe formed on the inner wall of the inside of the protective cap, and the convex stripe contacts with an outer circumferential surface of the ring-shaped portion of the inner cap, so that the inner cap is retained by the thus generated frictional force.

In the above configuration, preferably, on the outer surface of the front end portion of the male type connector, a convex stripe is formed so as to extend in the axis direction to a portion close to a joining portion between the guide groove and the circumferential direction step portion, and when the protective cap or the female type connector is combined with the male type connector, the convex stripe guides the guide protrusion of each of the protective cap and the female type connector to the guide groove.

The female type connector used in the above connector system for sterile connection includes a double-cylinder structure in which an inner cylinder is fixed at one end portion of an outer cylinder. The inner cylinder includes an internal end portion located inside the outer cylinder and an external end portion exposed outside the outer cylinder.

5

The protective cap assembled member used in the above connector system for sterile connection includes: the protective cap having a substantially cylindrical shape whose one end is closed; and the inner cap retained at an inside of the protective cap and including a ring-shaped portion with a disinfectant-impregnated member supported therein. On an inner wall of the inside of the protective cap, an inner cap retaining portion for retaining the inner cap is formed. The inner cap includes a plurality of engaging legs extending from an outer edge portion of the ring-shaped portion in a direction along an axis of the ring, and an engaging convexity is formed at each of the engaging legs so as to protrude inward. The inner cap is retained by the inner cap retaining portion so that the front ends of the engaging legs are directed toward an opening of the protective cap.

The male type connector used in the above connector system for sterile connection includes engaging concavities formed on an outer surface of the front end portion thereof so as to allow engagement with the engaging convexities formed at the engaging legs of the inner cap.

BRIEF DESCRIPTION OF THE DRAWINGS

FIGS. 1A to 1G are front cross-sectional views showing each element constituting a connector system for sterile connection according to one embodiment of the present invention and their operation.

FIG. 2 is a perspective view showing a male type connector constituting the connector system for sterile connection according to the embodiment of the present invention.

FIG. 3 is a front view showing the male type connector.

FIG. 4 is a cross-sectional view showing a protective cap constituting the connector system for sterile connection according to the embodiment of the present invention.

FIG. 5A is a perspective view showing an inner cap constituting the connector system for sterile connection, FIG. 5B is a plan view of the same and FIG. 5C is a cross-sectional view of the same.

FIG. 6 is a cross-sectional view showing a female type connector constituting the connector system for sterile connection.

FIG. 7 is a cross-sectional view of the female type connector in perspective.

FIGS. 8A to 8E are cross-sectional views illustrating the operation of fitting the protective cap with the patient side connector, which constitute the connector system for sterile connection according to the embodiment of the present invention.

FIGS. 9A to 9E are cross-sectional views illustrating the operation of connecting the male type connector and the female type connector according to the same.

DETAILED DESCRIPTION OF THE INVENTION

The following describes a configuration of a connector system for sterile connection according to one embodiment of the present invention, with reference to FIGS. 1 to 7. The present embodiment is described with respect to a peritoneal dialysis system as one example. In this embodiment the male type connector can be considered as on the patient side and the female type connector on the circuit side. "Patient side" and "circuit side" may be used in place of "male type" and "female type" respectively in the discussion of this embodiment. As indicated by an exploded view of FIG. 1A, this connector system for sterile connection includes a patient side connector 1, a protective cap 2, an inner cap 3 and a circuit side connector 4.

6

The patient side connector 1 is connected to a front end of an extension tube 5a that leads to a peritoneal catheter implanted in a patient's abdominal cavity. The circuit side connector 4 is connected to an extension tube 5b as a front end of a circuit in a container of dialysis solution, such as a twin bag, BF and APD. The inner cap 3 initially is supplied in a state of being supported in the protective cap 2, as shown on the right side of FIG. 1B. The inner cap 3 is equipped with a disinfectant-impregnated member, such as a disinfecting sponge impregnated with a disinfectant, which will be described later. The outline of a function of each element constituting this connector system for sterile connection will be described below, with reference to FIGS. 1B to 1G.

The patient side connector 1 is connected to the front end of the extension tube 5a, which is used during a long term use for a half year. The protective cap 2 is fitted with the patient side connector 1 always during daily activities for protecting the front end of the connector. For this purpose, as shown in FIG. 1B, the protective cap 2 that supports a newly-prepared inner cap 3 therein is opposed to the patient side connector 1, and they are fitted with each other as shown in FIG. 1C. In this state, the disinfectant-impregnated member provided in the inner cap 3 contacts with an end face of the patient side connector 1 so as to perform a disinfecting function.

When a dialysis solution is exchanged, firstly, the protective cap 2 is removed from the patient side connector 1. In this removal operation, the inner cap 3 is transferred from the protective cap 2 to the patient side connector 1 as shown in FIG. 1D. In this exchanging operation of the dialysis solution, as shown in FIG. 1E, the circuit side connector 4 is opposed to the patient side connector 1 and, as shown in FIG. 1F, is connected with the patient side connector 1, thus forming a channel leading from the twin bag or the like to the patient's abdominal cavity. When the dialysis solution has been exchanged, as shown in FIG. 1G, the connection between the patient side connector 1 and the circuit side connector 4 is released. Then, the inner cap 3 finally is transferred to the circuit side connector 4 in accordance with the operation that will be described later, and is discarded together with the circuit side connector 4.

Each of the above constituting elements will be described below in detail. The patient side connector 1, as shown in FIGS. 2 and 3, includes a substantially cylindrical-shaped main body 10 made of resin, a septum supporting member 11 made of resin, which is fitted to a front end of the main body 10, and an O ring 101. At a base end (rear end) of the main body 10, a tube-shaped tube connecting portion 12 is formed for the connection with the extension tube (not illustrated). On either side of the tube connecting portion 12, a knob 102 is provided for supporting firmly when the patient side connector 1 is rotated.

Inside the main body 10, a channel is formed so as to penetrate from its front end to the tube connecting portion 12. On an outer surface of the central portion of the main body 10, a guide groove 13 is formed. A pair of the guide grooves 13 is provided symmetrically with respect to the axis of the main body 10, and one of the guide grooves 13 is located on the reverse side of FIG. 2. The pair of guide grooves 13 is not necessarily required, and only one guide groove may function sufficiently. The guide groove 13 includes an axis direction portion 13a extending in the axis direction of the main body 10, an inclined portion 13b that is inclined and a circumferential portion 13c extending along the circumferential direction. The axis direction portion 13a on the front end side ends with a step portion 14 formed on

the outer surface of the main body **10**. The step portion **14** is formed in the circumferential direction so that an outer diameter of the main body **10** at the front end side becomes smaller than at the base end side.

On the outer surface of a front end portion of the main body **10**, an engaging concavity **15** is formed. The engaging concavity **15** is provided for supporting the inner cap **3** as indicated by alternate long and short dash lines in FIG. **3**. This structure will be further described later. The septum supporting member **11** has a fitting hole **16**, and the septum supporting member **11** is fixed to the main body **10** by the fitting between this fitting hole **16** and a protrusion **17** provided on the main body **10**. At a central portion of the septum supporting member **11**, a septum member such as a rubber septum (member with a slit) **18** is provided so as to protect the channel and ensure liquid-tightness. On a side surface of the septum supporting member **11** and a side surface of the front end portion of the main body **10**, blocking walls **19a** and **19b** respectively are formed. A convex stripe **19c** is provided for guiding a guide protrusion **21**, etc., formed on an inner wall of the protective cap **2**, which will be described later, to the axis direction portion **13a** of the guide groove **13**. Note here that the septum **18** is effective for ensuring liquid-tightness in the connecting state with the circuit side connector **4**, but this element is not essential. Therefore, the liquid-tight seal may be ensured by other methods. In such cases, since the septum supporting member **11** is not used, the blocking walls **19a**, **19b** and the convex stripe **19c** are formed directly on the main body **10**.

The protective cap **2** may be made of resin and, as shown in FIG. **4**, has a hollow structure with a substantially cylindrical shape whose front end is closed. On an inner wall close to an opening **20** of the protective cap **2**, a guide protrusion **21** is formed and located on a projected portion **22** that projects like a rectangular island. A rotation-blocking step portion **22a** is formed with an edge of the projected portion **22** along the axis direction. Although a pair of the guide protrusions **21** and a pair of the projected portions **22** are provided symmetrically, only one of them is illustrated in this drawing. On an inner circumferential surface of the closed end of the protective cap **2**, a convex stripe **23** is formed. At this portion, the inner cap **3** is placed as indicated by the alternate long and short dash lines, and the inner cap **3** is supported by frictional engagement between the outer circumferential surface of a ring-shaped portion **30** (FIG. **5**) of the inner cap **3** and the convex stripe **23**. By inserting the patient side connector **1** into the opening **20**, the protective cap **2** is fitted with the front end of the patient side connector **1**. In this operation, the guide protrusion **21** engages with the guide groove **13** in the patient side connector **1**, and a mutual positional relationship between the protective cap **2** and the patient side connector **1** is guided by the engagement, so that the fitting is conducted. This operation will be described later.

The inner cap **3** may be made of resin and, as shown in FIGS. **5A-C**, includes the ring-shaped portion **30** and two engaging legs **31**. Inside the ring-shaped portion **30**, a disinfecting sponge **32** is installed. Inside the ring-shaped portion **30**, inward protrusions **30a** and **30b** are formed at plural portions. The inward protrusions **30a** are arranged at an upper end in the axis direction, whereas the inward protrusions **30b** are arranged at a lower end in the axis direction. Between the inward protrusions **30a** and **30b**, the disinfecting sponge **32** is supported. A straight-line or cross-shaped slit (not illustrated) may be provided in the disinfecting sponge **32** so that an internal end portion **41b** of the circuit side connector **4**, which will be described later, can

penetrate therethrough, and the disinfecting sponge **32** is impregnated with a disinfectant such as Isodine. The engaging legs **31** protrude outward in the radial direction from the outer circumferential surface of the ring-shaped portion **30**. At a front end of each of the engaging legs **31**, an engaging convexity **33** is formed so as to protrude inward. As previously described, the inner cap **3** initially is held in the protective cap **2** as shown in FIG. **4**. When the protective cap **2** is fitted with the patient side connector **1**, the engaging convexity **33** of the inner cap **3** engages with the engaging convexity **15** of the patient side connector **1**. Thereby, the inner cap **3** is retained on the septum supporting member **11**.

As stated above, the inner cap **3** is retained in the protective cap **2** by the friction engagement with the convex stripe **23** in the protective cap **2**. Also, the inner cap **3** is retained on the patient side connector **1** by the engagement between the engaging concavity **15** of the patient side connector **1** and the engaging convexity **33** of the inner cap **3**. These modes for retaining the inner cap **3** are set so that the retaining force by the friction engagement in the protective cap **2** becomes smaller than the retaining force on the patient side connector **1**.

FIGS. **6** and **7** show the structure of the circuit side connector **4**. As shown in FIG. **6**, the circuit side connector **4** has a double-cylinder structure made of resin, in which an inner cylinder **41** is fixed at one end portion of an outer cylinder **40**. Note here that FIG. **7** omits the inner cylinder **41**. The outer cylinder **40** is open at a lower end in this drawing to constitute a front end portion of the circuit side connector **4**. The inner cylinder **41** includes an external end portion **41a** exposed outside the outer cylinder **40** and the internal end portion **41b** located inside the outer cylinder **40**. The external end portion **41a** is to be connected with a tube as the front end of the circuit in the container of dialysis solution. When connecting the circuit side connector **4** and the patient side connector **1**, the internal end portion **41b** pushes and expands the slit in the disinfecting sponge **32** in the inner cap **3** fitted with the patient side connector **1** and the slit in the rubber septum **18** supported by the septum supporting member **11** so as to penetrate through the patient side connector **1**, whereby the channel is opened.

On an inner wall of the opening end portion (the lower end portion in the drawings) of the outer cylinder **40**, a guide protrusion **42** is formed in the same manner as the guide protrusion **21** formed in the protective cap **2**. Also on the inner wall of the outer cylinder **40**, a guide step portion **43** is formed so as to extend from the lower end portion to the central portion. The guide step portion **43** includes, as clearly illustrated in FIG. **7**, clearance step portions **43a** and **43b**, an inclined step portion **43c** and a horizontal step portion **43d**, whose shapes and arrangement are set suitably for their functions that will be described later.

The horizontal step portion **43d** functions as means for retaining the inner cap **3** at an inside (an upper end portion in these drawings) of the outer cylinder **40**. That is, when the inner cap **3** is pushed into the inside of the outer cylinder **40** and the front ends of the engaging legs **31** contact with the horizontal step portion **43d**, the inner cap **3** is retained there. The operation for the same will be described later. Alternatively, another retaining means may be configured so that at least portions of an inner wall **45** of the inside of the outer cylinder **40** contact with an outer circumferential surface of the ring-shaped portion **30** of the inner cap **3**, whereby the inner cap **3** is retained by the thus generated frictional force. For such function, inward protrusions formed at plural portions on the inner wall **45** of the inside are effective. Alternatively, a plurality of outward protrusions

sions 46 may be provided on an outer wall of the internal end portion 41b of the inner cylinder 41 so as to contact with an inner circumferential surface of the ring-shaped portion 30 of the inner cap 3, whereby the inner cap 3 is retained by the thus generated frictional force.

In a state before use, a breakable film (not illustrated) is provided at the front end portion of the outer cylinder 40 of the circuit side connector 4 for protecting the inner cylinder and the channel in the circuit side connector 4 until immediately before use. At a rear end portion of the outer cylinder 40, operating knobs 44 are formed along the external end portion 41a of the inner cylinder 41.

Next, the operation of the connector system for sterile connection having the above configuration will be described below. Note here that the specification and claims may refer to rotation or other movement of a particular element for a simpler description, but that it should be understood that this is defining relative movement between the elements, and that either one of the elements can be moved and either one fixed, or both moved, to accomplish the relative movement.

Firstly, the operation for fitting the protective cap 2 with the patient side connector 1 will be described, with reference to FIG. 8. FIGS. 8A to 8D illustrate each state during an operation in which the patient side connector 1 is rotated while the protective cap 2 is fixed. The protective cap 2 is illustrated in a state rotated around the axis by 90° from the state shown in FIG. 4. The patient side connector 1 of FIG. 8A is in a state rotated around the axis by 90° clockwise from the angle shown in FIG. 3. From this state, by rotating the patient side connector 1 clockwise by 90° when viewed from the left side, the state of FIG. 8D is obtained. FIG. 8E shows a state where the protective cap 2 is rotated by 90° from the state shown in FIG. 8D.

To begin with, as shown in FIG. 8A, a newly-prepared protective cap 3 that retains an inner cap 3 therein is opposed to the patient side connector 1, and then as shown in FIG. 8B, the patient side connector 1 is inserted into the protective cap 2. During this operation, the guide protrusion 21 formed on the inner wall of the protective cap 2 contacts with the step portion 14 on the outer surface of the patient side connector 1 (See FIGS. 2 to 4). By rotating the protective cap 2 relative to the patient side connector 1, the guide protrusion 21 contacts with the convex stripe 19c, so that the guide protrusion 21 faces a portion of the axis direction portion 13a of the guide groove 13. With this operation, the patient side connector 1 becomes capable of being inserted further into the protective cap 2. From this position, the patient side connector 1 is pushed inside, and as shown in FIG. 8C, the patient side connector 1 further is rotated clockwise. That is, the operation is conducted so that the guide protrusion 21 slides along the inclined portion 13b of the guide groove 13. With this operation, by a screw action through the engagement between the guide protrusion 21 and the guide groove 13, the patient side connector 1 is pulled into the innermost of the protective cap 2. By rotating further, the guide protrusion 21 enters into the circumferential portion 13c. As a result, by the engagement of the guide protrusion 21 and the circumferential portion 13c, the protective cap 2 and the patient side connector 1 are combined so as not to separate from each other in the axis direction.

During this operation, the front end portion of the patient side connector 1 pushes the engaging legs 31 of the inner cap 3 outward. The inner cap 3 is prevented from rotating because the engaging legs 31 are blocked by the rotation-blocking step portion 22a of the protective cap 2, so that the engaging convexities 33 of the engaging legs 31 slide on the

outer circumferential surface of the front end portion of the patient side connector 1. Finally, as shown in FIG. 8D, the engaging convexities 33 engage with the engaging concavities 15 of the patient side connector 1. In this state, the disinfecting sponge 32 in the inner cap 3 continues to disinfect the septum 18 at the front end of the patient side connector 1 while a patient engages in daily activities. In addition, since the inner circumferential surface of the open end of the protective cap 2 contacts with the O ring 101, the liquid-tightness inside the protective cap 2 can be maintained and the front end of the patient side connector 1 can be protected from the air.

Next, the operation for removing the protective cap 2 from the state shown in FIG. 8D to exchange the dialysis solution will be described below. By rotating the protective cap 2 opposite to the direction for the fitting, the inner cap 3 rotates with respect to the protective cap 2 together with the patient side connector 1 by the retaining due to the engagement between the engaging convexities 33 and the engaging concavities 15 of the patient side connector 1. With this rotation, the guide protrusion 21 of the protective cap 2 slides along the guide groove 13 and reaches a junction between the axis direction portion 13a and the step portion 14. From this state, by separating the patient side connector 1 from the protective cap 2 in the axis direction, the patient side connector 1 is removed from the protective cap 2 while the inner cap 3 is fitted with the front end of the patient side connector 1 so as to assume a state shown in FIG. 8E.

Next, the operation for connecting the patient side connector 1 and the circuit side connector 4 will be described below, with reference to FIG. 9. FIGS. 9A to 9D illustrate each state during an operation in which the circuit side connector 4 is rotated while the patient side connector 1 is fixed. The patient side connector 1 is illustrated in the same angle as in FIG. 8E. The circuit side connector 4 of FIG. 9A is illustrated in the angle of FIG. 6. By rotating the circuit side connector 4 by 90° counterclockwise when viewed from the patient side connector 1 side, the state of FIG. 9D is obtained. FIG. 9E illustrates a state where the patient side connector 1 is rotated by 90° from the state shown in FIG. 9D.

Firstly, as shown in FIG. 9A, the patient side connector 1 and the circuit side connector 4 are opposed to each other. In this state, the inner cap 3 is fitted with the front end of the patient side connector 1. Next, as shown in FIG. 9B, the patient side connector 1 is inserted into the circuit side connector 4. In this operation, the guide protrusion 42 formed on the inner wall of the circuit side connector 4 contacts with the step portion 14 on the outer surface of the patient side connector 1. The circuit side connector 4 is rotated properly so that the guide protrusion 42 faces a position on a junction between the axis direction portion 13a of the guide groove 13 and the step portion 14, whereby the patient side connector 1 becomes capable of being inserted further into the circuit side connector 4. In this state, the engaging legs 31 of the inner cap 3 are located on the right side of the clearance step portions 43a and 43b shown in FIG. 7. Therefore, when the patient side connector 1 further is inserted, the engaging legs 31 are located to escape from the guide step portion 43.

In order to insert the patient side connector 1 into an inside, the patient side connector 1 is pushed inward from this position, while rotating the circuit side connector 4 clockwise. With this operation, the guide protrusion 42 slides along the inclined portion 13b of the guide groove 13. According to a screw action generated between the guide protrusion 42 and the guide groove 13, the patient side

11

connector **1** reaches the inside of the circuit side connector **4** as shown in FIG. 9C. By rotating further, the guide protrusion **42** enters into the circumferential portion **13c**.

During the process of the guide protrusion **42** sliding along the circumferential portion **13c**, the front ends of the engaging legs **31** of the inner cap **3** that is fitted with the front end of the patient side connector **1** contact with the inclined step portion **43c**. By the rotational force exerted through the contact between the side surfaces of the engaging legs **31** and the blocking walls **19a** and **19b** of the patient side connector **1**, the front ends of the engaging legs **31** slide along the inclined step portion **43c**. Thereby, the inner cap **3** receives a force in the axis direction toward an inside of the circuit side connector **4** from the inclined step portion **43c**. As a result, as shown in FIG. 9D, the engagement between the engaging convexities **33** formed at the front ends of the engaging legs **31** of the inner cap **3** and the engaging concavities **15** of the patient side connector **1** is released. Finally, the front ends of the engaging legs **31** reach the horizontal step portion **43d**, and the inner cap **3** is retained in the circuit side connector **4** in this state. That is to say, when the patient side connector **1** is rotated counterclockwise to release the connection between the patient side connector **1** and the circuit side connector **4**, the inner cap **3** is not rotated because the engagement between the engaging concavities **15** and the engaging convexities **33** has been released. Moreover, since the front ends of the engaging legs **31** and the horizontal step portion **43d** are engaged, the inner cap **3** does not move in the axis direction so as to be detached from the circuit side connector **4**.

In addition, when the circuit side connector **4** and the patient side connector **1** are connected as described above, the internal end portion **41b** of the inner cylinder **41** of the circuit side connector **4** pushes and expands the slit in the disinfecting sponge **32** in the inner cap **3** fitted with the front end of the patient side connector **1** and the slit in the rubber septum **18** supported by the septum supporting member **11** so as to penetrate through the patient side connector **1**, whereby the channel is opened. In this process, the channel is formed while the inner cylinder **41** is disinfected by the disinfecting sponge **32**.

After the draining and filling of the peritoneal dialysis solution have been completed, when the circuit side connector **4** is removed, the patient side connector **1** is rotated counterclockwise. With this operation, the engagement between the guide protrusion **42** and the guide groove **13** is released, and therefore the connection between both connectors is released. In this operation, as described above, the inner cap **3** is left in the circuit side connector **4** (FIG. 9E).

After that, by fitting a newly-prepared protective cap **2**, a new inner cap **3** is fitted with the front end of the patient side connector **1**, whereby as stated above the front end portion of the patient side connector **1** continues to be disinfected until the next exchanging operation of the dialysis solution.

The invention may be embodied in other forms without departing from the spirit or essential characteristics thereof. The embodiments disclosed in this application are to be considered in all respects as illustrative and not limiting. The scope of the invention is indicated by the appended claims rather than by the foregoing description, and all changes which come within the meaning and range of equivalency of the claims are intended to be embraced therein.

What is claimed is:

1. A connector system for sterile connection comprising: a male type connector including a tube connecting portion at a rear end portion thereof;

12

a protective cap having a substantially cylindrical shape with a closed first end and being capable of connecting and disconnecting with/from a front end side of the patient side connector;

an inner cap including a ring-shaped portion that supports a disinfectant-impregnated member therein, the inner cap being retained inside the protective cap in an initial state; and

a female type connector having a double-cylinder structure in which an inner cylinder is fixed at one end portion of an outer cylinder, the inner cylinder including an internal end portion located inside the outer cylinder and an external end portion exposed outside the outer cylinder and capable of connecting with a tube,

wherein a channel for solution is connected by fitting the outer cylinder of the female type connector with the male type connector,

when the protective cap is fitted with the male type connector, the inner cap assumes a state of being retained at the front end side of the male type connector,

when the protective cap is removed from the male type connector, the inner cap is detached from the protective cap because of a retaining force at the front end side of the male type connector,

when the patient side connector with the inner cap retained at the front end thereof is connected with the female type connector, the internal end portion of the inner cylinder penetrates through the disinfectant-impregnated member in the inner cap, so that the channel is opened, and

when the connection between the male type connector and the female type connector is released, the inner cap is retained inside the female type connector and is detached from the front end of the male type connector.

2. The connector system for sterile connection according to claim 1,

wherein the male type connector comprises a septum member at a front end portion thereof for protecting the channel, and

when the patient side connector with the inner cap retained at the front end thereof is connected with the female type connector, the internal end portion of the inner cylinder penetrates through the disinfectant-impregnated member in the inner cap and the septum member of the male type connector, so that the channel is opened.

3. The connector system for sterile connection according to claim 1,

wherein the inner cap comprises a plurality of engaging legs extending from an outer edge portion of the ring-shaped portion in a direction along an axis of the ring, an engaging convexity is formed at a front end of each of the engaging legs so as to protrude inward, engaging concavities are formed on an outer surface of the front end portion of the patient side connector so as to allow engagement with the engaging convexities formed at the engaging legs of the inner cap, an inner cap retaining portion is formed on an inner wall inside the protective cap, where a retaining force exerted by the engagement between the engaging convexity of the inner cap and the engaging concavity of the male type connector is larger than a force exerted by the inner cap retaining portion of the protective cap to retain the inner cap,

13

when the protective cap with the inner cap retained therein is fitted with the male type connector, the engaging convexities of the inner cap engage with the engaging concavities of the male type connector, and when the protective cap is removed from the male type connector, the retaining of the inner cap by the inner cap retaining portion of the protective cap is released due to the retaining of the inner cap at the engaging concavities of the male type connector, so that the inner cap is detached from the protective cap while being fitted with the front end of the male type connector.

4. The connector system for sterile connection according to claim 3,

wherein on the outer surface of the male type connector, a circumferential step portion extending in a circumferential direction is formed so that a diameter at the front end side of the male type connector is smaller than that at a base end side, and a guide groove is formed so as to extend from the circumferential step portion toward the base end, the guide groove including an inclined portion that is inclined with respect to an axis of the male type connector,

on the inner wall close to an opening end portion of the protective cap, a guide protrusion is formed, and on the inner wall and extending toward the closed end side of the protective cap, a rotation blocking step portion is formed, the rotation blocking step portion being capable of contacting with the engaging legs of the inner cap so as to block a rotational action of the inner cap,

when the male type connector is inserted into an opening of the protective cap with the guide protrusion of the protective cap facing the guide groove of the male type connector, and then the protective cap and the male type connector are rotated while being urged axially toward each other, the guide protrusion slides along the guide groove, so that the male type connector is pulled into an inside of the protective cap by a driving force resulting from a screw action by the inclined portion of the guide groove, and the engaging convexities of the inner cap, whose rotation is blocked by the rotation blocking step portion, engage with the engaging concavities of the male type connector.

5. The connector system for sterile connection according to claim 4,

wherein the male type connector comprises a blocking wall at the front end portion thereof, which is capable of contacting with a side face portion of the engaging leg of the inner cap when the inner cap is fitted thereto, and the outer cylinder of the female type connector comprises: a guide protrusion formed on an inner wall close to an open end portion thereof, the guide protrusion being formed to correspond to the guide protrusion of the protective cap; a guide step portion including an inclined portion that is inclined with respect to an axis of the female type connector; and an inner cap retaining portion formed at an inside of the connector and being capable of retaining the inner cap,

when the male type connector with the inner cap retained therein is inserted into the opening of the female type connector with the guide protrusion of the outer cylinder facing the guide groove of the male type connector, and then the female type connector and the male type connector are rotated while being urged axially toward each other, the guide protrusion slides along the guide groove, so that the male type connector

14

is pulled into the inside of the female type connector by a driving force resulting from a screw action by the inclined portion of the guide groove, and at the same time the front ends of the engaging legs of the inner cap slide along the inclined portion of the guide step portion of the female type connector while rotation of the inner cap is blocked by the blocking wall of the male type connector, so that a force in the axis direction acts on the inner cap so as to separate the inner cap from the male type connector, resulting in release of the engagement between the inner cap and the male type connector, and the inner cap assumes a state of being retained by the inner cap retaining portion of the outer cylinder.

6. The connector system for sterile connection according to claim 5,

wherein the inner cap retaining portion of the female type connector is configured with a horizontal step portion provided at the innermost of the guide step portion, and when the front ends of the engaging legs of the inner cap contact with the horizontal step portion, the inner cap is prevented from moving in the axis direction toward the opening of the outer cylinder so as to be retained in the female type connector.

7. The connector system for sterile connection according to claim 5,

wherein the inner cap retaining portion of the female type connector is configured by setting dimensions of constituting elements so that at least portions of the inner wall of the inside of the outer cylinder contact with an outer circumferential surface of the ring-shaped portion of the inner cap or so that at least portions of the outer wall of the internal end portion of the inner cylinder contact with an inner circumferential surface of the ring-shaped portion of the inner cap, whereby the inner cap is retained by the thus generated frictional force.

8. The connector system for sterile connection according to claim 3,

wherein the inner cap retaining portion of the protective cap is configured with a convex stripe formed on the inner wall of the inside of the protective cap, and

the convex stripe contacts with an outer circumferential surface of the ring-shaped portion of the inner cap, so that the inner cap is retained by the thus generated frictional force.

9. The connector system for sterile connection according to claim 4,

wherein on the outer surface of the front end portion of the male type connector, a convex stripe is formed so as to extend in the axis direction to a portion close to a joining portion between the guide groove and the circumferential direction step portion, and

when the protective cap or the female type connector is combined with the male type connector, the convex stripe guides the guide protrusion of each of the protective cap and the female type connector to the guide groove.

10. The female type connector used in the connector system for sterile connection according to claim 1, comprising a double-cylinder structure in which an inner cylinder is fixed at one end portion of an outer cylinder, the inner cylinder including an internal end portion located inside the outer cylinder and an external end portion exposed outside the outer cylinder.

15

11. The protective cap assembled member used in the connector system for sterile connection according to claim **3**, comprising:

the protective cap having a substantially cylindrical shape whose one end is closed; and

the inner cap retained at an inside of the protective cap and including a ring-shaped portion with a disinfectant-impregnated member supported therein,

wherein on an inner wall of the inside of the protective cap, an inner cap retaining portion for retaining the inner cap is formed,

the inner cap includes a plurality of engaging legs extending from an outer edge portion of the ring-shaped

5

10

16

portion in a direction along an axis of the ring, and an engaging convexity is formed at each of the engaging legs so as to protrude inward, and

the inner cap is retained in the inner cap retaining portion so that the front ends of the engaging legs are directed toward an opening of the protective cap.

12. The male type connector used in the connector system for sterile connection according to claim **3**, comprising engaging concavities formed on an outer surface of the front end portion thereof so as to allow engagement with the engaging convexities formed at the engaging legs of the inner cap.

* * * * *